Zacks Small-Cap Research

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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: Adjusting PT to $25 reflecting reverse stock split; Phase III of SGX-*301 initiated in collaboration with NORD and CLF,* Positive data reported from Phase II of SGX942 for oral mucositis

Current Price (10/06/16)	$7.50
Valuation	**$25.00**

OUTLOOK

SNGX is a late stage biopharmaceutical company focused on cancer/cancer supportive care, GI disorders and biodefense. Based on three platform technologies, SNGX has built a diversified pipeline targeting multiple indications. We are optimistic about its lead candidates SGX301for CTLC and SGX942 for the treatment of oral mucositis. The Company's oral BDP is in various development stages for a variety of indications, most notably, in pediatric Crohn's disease, where they will be initiating a Phase III study soon for SGX203. SNGX also is developing vaccines using its ThermoVax technology for biodefense.

Valuation is attractive at this time based on the fundamentals.

SUMMARY DATA

52-Week High	**$14.3**
52-Week Low	**$5.20**
One-Year Return (%)	**-47.15**
Beta	**2.79**
Average Daily Volume (sh)	**69,589**
Shares Outstanding (mil)	**3.4**
Market Capitalization ($mil)	**$20**
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 E	3.0 E	11.8 E
2017					11.0 E
2018					24.0 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	-$0.87 E	-$0.95 E	-$2.76 E
2017					-$2.50 E
2018					

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

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WHAT'S NEW

Adjusting Our Price Target to Reflect One-for-Ten Reverse Split

We adjust our price target to **$25 per share** to reflect the **one-for-ten reverse stock split**.

On Oct. 7, 2016, Soligenix announced a one-for-ten (1:10) reverse stock split which was implemented by the Company in preparation for its proposed **up-listing** of the Company's common stock to the NASDAQ Capital Market.

The reverse split improves Soligenix's capital structure and creates a more appealing stock price, thereby, increasing the Company's likelihood of achieving its goal of qualifying for up-listing. Importantly, it also has the potential to better facilitate a multitude of strategic initiatives, including partnership, merger and acquisition, as well as equity financing.

Up-listing is a key milestone for the company's growth. The NASDAQ listing is expected to facilitate greater liquidity in the stock as well as enable broader access to the investment community, many participants of which are unable to buy stock listed on the bulletin board.

We remain optimistic about Soligenix's long term prospect. We believe there are multiple catalysts to drive the share price up in the next 6 to 12 months.

Soligenix becomes a late development stage biotech company through the acquisition of SGX301, a Phase III candidate for CTLC. Soligenix is focused on **cancer/cancer supportive** care and **GI disorders**, two large pharmaceutical markets both in the US and around the world. Soligenix also develops vaccines/oral therapeutics for **biodefense**.

In addition to SGX301, Soligenix has built a diversified pipeline using three proprietary platform technologies: the **SGX942** platform, the **oral BDP** platform and the **ThermoVax** platform. We are optimistic about its drug candidate SGX942 for the treatment of mucositis. The preliminary positive data reported from the Phase II trial is a significant **de-risking** event for Soligenix. SGX942 has a new mechanism of action and will command a significant market share of the oral mucositis market if approved in our view.

The Company's oral BDP has the potential to target multiple GI disorders such as Crohn's disease, radiation enteritis and GVHD as well as ARS.

Soligenix's vaccines and biodefense therapeutics are being developed under specific FDA regulatory guidelines called the "**Animal Rule**." We think the "Animal Rule" means a lot for Soligenix, because this can accelerate the development of the ricin and anthrax vaccines as well as OrbeShield. Once approved by the FDA, Soligenix will have the opportunity to negotiate a stock-pile contract with the US government. These stock-pile or procurement contracts have been very lucrative for other companies supplying similar drugs to the US government and will provide significant cash flow to Soligenix.

Based on our analysis, we believe Soligenix shares are undervalued at current market price. Currently shares of Soligenix are trading at around $0.60 per share, which values the Company at $21 million in market cap based on 33 million outstanding shares. This deeply undervalues Soligenix shares in our view.

Our price target of $25 per share values Soligenix at $85 million in market cap which we think is very conservative.

Update on Second Quarter Financials

On August 11, Soligenix reported financial results for the second quarter ended June 30, 2016.

Total revenue for the second quarter was $3.2 million, as compared to $1.1 million for the same period for the prior year. Revenues included contracts with BARDA and NIAID in support of OrbeShield® development in the treatment of GI ARS and advanced development of the Company's thermostabilization technology, ThermoVax®, combined with its ricin toxin vaccine RiVax™, as a medical countermeasure to prevent the effects of ricin exposure.

R&D expenses for 2Q16 were $0.8 million, as compared to $1.4 million for the quarters ended June 30, 2015. The decrease was related to completion of patient enrollment and treatment in the Phase II trial of SGX942 for the treatment of oral mucositis in head and neck cancer. The long-term follow-up safety data from this trial continues to be collected, with completion expected during the second half of 2016.

G&A expenses for the second quarter of 2016 were $1.0 million as compared to $0.9 million for the quarters ended June 30, 2015.

Net loss for 2Q16 was $0.1 million ($0.00 per share), as compared to $4.0 million ($0.15 per share) for the same period last year. Included in the net loss for quarters ended June 30, 2016 and 2015 is non-cash income of $0.9 million and a non-cash expense of $1.9 million, respectively. This non-cash item reflects the change in fair value of the liability related to warrants issued in the Company's June 2013 registered public offering and is included in other income/(expense).

Adjusted net loss for 2Q16 was $1.0 million ($0.03 per share), compared to net loss of $2.0 million ($0.08 per share).

As of June 30, 2016, the Company's cash position was $3.2 million.

Orphan Drug Designation Granted for Dusquetide for Treatment of Macrophage Activation Syndrome

On Aug. 18, 2016, Soligenix announced that the FDA has granted **orphan drug designation** to **dusquetide** for treatment of **macrophage activation syndrome** (MAS). Dusquetide has previously received orphan drug designation for the treatment of acute radiation syndrome (ARS).

Dusquetide (SGX942), the company's lead candidate, is an innate defense regulator (IDR), a new class of short, synthetic peptides that accelerates bacterial clearance and resolution of tissue damage while modulating inflammation following exposure to a variety of agents including bacterial pathogens, trauma, radiation and/or chemotherapy.

In addition to providing a **seven-year term of market exclusivity** upon final FDA approval, orphan drug designation also positions Soligenix to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of expensive FDA user fees for the potential submission of a New Drug Application, and certain tax credits.

Macrophage activation syndrome (MAS) is characterized by a highly stimulated but ineffective immune response; however, its pathogenesis is poorly understood. MAS has many similarities with that of the other forms of hemophagocytic lymphohistiocytosis. MAS is a life-threatening complication of rheumatic disease that, for unknown reasons, occurs much more frequently in individuals with systemic juvenile idiopathic arthritis (SJIA). Besides SJIA, systemic lupus erythematosus (SLE), and Kawasaki disease are two other rheumatologic conditions in which MAS appears to occur somewhat more frequently than in other diseases. In adults, based on limited epidemiologic studies, MAS is seen most frequently in association with adult onset Still's disease, SLE, and various vasculitic syndromes. MAS is characterized by pancytopenia, liver insufficiency, coagulopathy and neurologic symptoms and is thought to be caused

by the activation and uncontrolled proliferation of T lymphocytes and well-differentiated macrophages, leading to widespread hemophagocytosis and cytokine overproduction. Despite treatment, fatalities still occur with a mortality rate in the range of 10-20%.

Dusquetide's activity in preclinical models has demonstrated the potential to enhance mechanisms of the innate immune system to clear infection and modulate the inflammatory response, the critical attributes of the MAS. This gives Soligenix the opportunity to **expand the pipeline into a new indication for dusquetide**.

Additional BARDA and NIAID Funding to Advance Development of OrbeShield® in GI ARS

On July 25, 2016, Soligenix (SNGX) announced that the company has been granted **additional funding** from the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

The additional funding totals $634,000 ($284,000 from NIAID and $350,000 from BARDA) and will support **preclinical** development of Soligenix **OrbeShield®** as a medical countermeasure (MCM) for civilian and military use in treatment of gastrointestinal acute radiation syndrome **(GI ARS).**

OrbeShield™ is an oral BDP (beclomethasone 17,21-dipropionate) formulation which represents a first-of-its-kind oral, locally acting therapy tailored to treat **gastrointestinal inflammation**.

BDP is a **corticosteroid** that has been marketed in the U.S. and worldwide since the early 1970s via other methods of delivery.

- Inhaled forms for asthma such as Clenil, Qvar
- Nasal forms for rhinitis such as Beconase, Alanase, Vancenase
- Creams for severe inflammatory skin disorders such as Propaderm

Soligenix's oral BDP is specifically formulated for oral administration including SGX203, SGX201, orBec, and OrbeShield. Each is designed as potent, topically active corticosteroid to treat GI inflammation and provide superior safety profile.

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in Soligenix's acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a "dual use" compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications.

Soligenix's GI ARS program is supported by contract awards from both BARDA and NIAID, totaling up to approximately $33 million with the supplemental funding if all options are exercised. To date, exercised funds have included $7 million from NIAID and $11 million from BARDA, including all additional funds.

Oral BDP has orphan drug designations in the U.S. and in Europe. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S. and Europe, respectively.

SNGX Announces Positive Results of a Heat Stable Ebola Vaccine Formulation

On July 18, 2016, Soligenix (SNGX) announced **positive preliminary proof-of-concept results** from a heat stable subunit **Ebola vaccine**.

This is a collaboration with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai□i at Mānoa (UH Mānoa) and Hawaii Biotech, Inc. (HBI).

Soligenix's ThermoVax Technology is used in this collaboration and has identified a formulation that enhances the physical stability of the protein and may be dose sparing.

Dr. Lehrer has shown proof of concept efficacy with subunit Ebola vaccines in **non-human primates.** Soligenix evaluated its proprietary vaccine **thermostabilization technology**, ThermoVax® to stabilize components of the vaccine. These studies identified a formulation that maintained the physical state of the Ebola subunit protein despite incubation at **40 degrees Celsius** (104 degrees Fahrenheit) for 12 weeks.

Moreover, initial testing revealed that two doses of this new formulation is as effective as three doses of a non-stabilized vaccine in generating antibodies to Ebola, even after storage at 40 degrees Celsius for 12 weeks. Further studies evaluating the protective ability of the vaccines are planned. Ultimately, the objective is to produce a thermostable Ebola vaccine for worldwide distribution that does not require cold storage.

In **preclinical studies**, ThermoVax® has been previously demonstrated to enhance thermostability of ricin (RiVax™), anthrax and human papillomavirus (HPV) subunit vaccines.

The most advanced Ebola vaccines involve complicating manufacturing process which lead to stability and storage requirements. Dr. Lehrer's vaccine is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax®may can avoid the need for cold-chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world.

Results from the Ebola development studies will be presented in a poster entitled "Thermostable Lyophilized Ebola Vaccine Formulations" at the 2016 Workshop on Protein Aggregation and Immunogenicity, on August 2-4, 2016 in Breckenridge, Colorado.

We are pleased to see the positive preliminary results from the Ebola vaccine, especially the successful application of Soligenix's thermostabilization technology. SNGX continues to demonstrate the broad applicability of the ThermoVax® heat stabilization platform.

Additional NIAID Funding Received to Advance Development of Ricin Vaccine

On **May 25, 2016**, Soligenix announced today that the National Institute of Allergy and Infectious Diseases (NIAID) has exercised an option for the evaluation of RiVax™ to fund animal efficacy and toxicology studies.

The exercised option for **contract #HHSN272201400039C** will provide Soligenix with an additional $3.2 million in funding. If all contract options are exercised, the total award of up to $24.7 million will support the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax™ with the FDA.

In **early May, 2016**, the NIAID exercised an option for RiVax™ bulk drug substance and finished drug product process scale-up and technology transfer that will support preclinical studies and manufacturing in accordance with current good manufacturing practices (cGMPs). The exercised option for the same contract will provide Soligenix with an additional $4.3 million in funding.

The overall objectives of the contract are to advance the development of Soligenix's thermostabilization technology, ThermoVax®, combined with the company's ricin toxin vaccine, RiVax™, as a medical countermeasure to prevent the effects of ricin exposure.

We think the exercise of the options not only boosts Soligenix's balance sheet, more importantly, it validates Soligenix's vaccine technology and its ongoing commitment to advance development of viable thermostabilization vaccines.

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 entitled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations."

The US Centers for Disease Control and Prevention (CDC) estimate the lethal dose in humans is about the size of a grain of salt. Ricin toxin illness causes tissue necrosis and general organ failure leading to death within several days of exposure. Ricin is especially toxic when inhaled. Ricin works by getting inside the cells of the body and preventing the cells from making the proteins it needs.

There are currently no effective treatments for ricin poisoning. The successful development of an effective vaccine against ricin toxin may act as a deterrent against the actual use of ricin as a biological weapon and could be used in rapid deployment scenarios in the event of a biological attack.

Update on SGX942 for Mucositis

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

On June 25, 2016, the Company presented the data at the Multinational Association for Supportive Care in Cancer (MASCC) conference in Adelaide, Australia.

The Phase II Trial

In December, 2013, SNGX initiated the **Phase II** study of SGX942 (NCT02013050) for the treatment of **oral mucositis** in head and neck cancer patients.

This Phase II trial is a randomized, double-blind, dose-ranging, placebo-controlled trial, initially set to enroll approximately **75 subjects** across three SGX942 dose groups (1.5 mg/kg, 3.0 mg/kg and 6.0 mg/kg) and placebo, focused on demonstrating the safety and biologic activity of SGX942 in patients with tumors of the mouth and oropharynx who often experience debilitating oral mucositis as a consequence of tumor treatment with chemoradiation therapy (CRT).

In early March 2015, Soligenix received a positive recommendation from the Data Review Committee (DRC) to continue the enrollment. Following DRC review of available data on the subjects enrolled in the trial, the committee recommended that enrollment include an **additional 20 subjects** randomized into either a single SGX942 dose group or the placebo group to allow for a more targeted assessment of the drug's potential effect and to inform final dose selection in this patient population.

The **primary efficacy** assessment is the comparison of the incidence and/or duration of both ulcerative and severe oral mucositis throughout the subjects' 7 week course of CRT and for an additional 4 weeks thereafter. **Other key efficacy** measures will assess patient reported outcomes, pharmacoeconomic parameters such as hospitalization and radiation-associated side effects including mouth stiffness and dryness.

In August 2015, the trial completed the expanded enrollment.

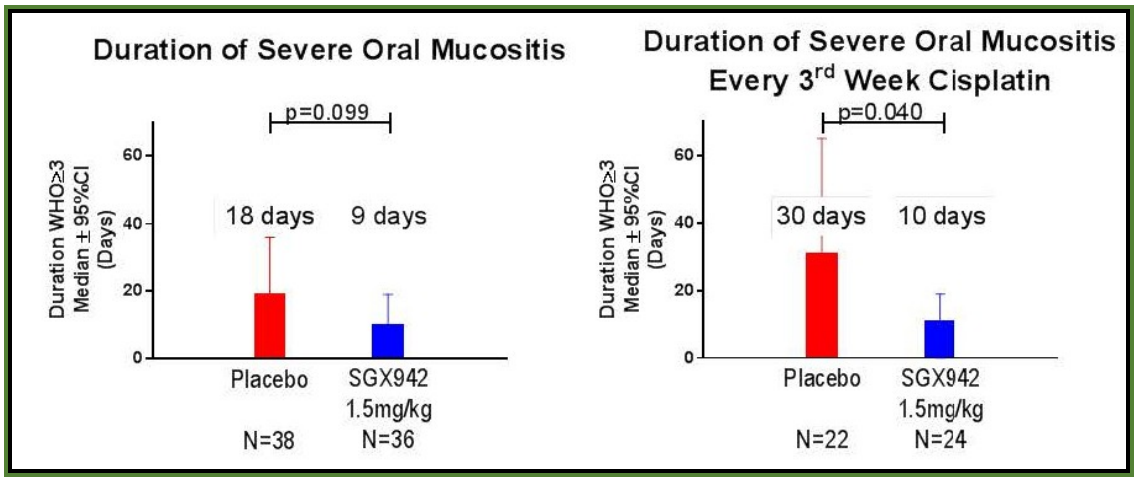
The Positive Data

The Phase II study (NCT02013050) 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.

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

The 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 has 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.

SGX942 has received fast-track designation from the FDA.

The Next Step

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

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

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

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

SGX942 belongs to a new class of compounds called **Innate Defense Regulators (IDRs)** which 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 **tissue damages** and **infections**.

Recently, we interviewed **Dr. Stephen T. Sonis**, DMD, DMSc with regard to his view on oral mucositis and biotech company Soligenix's lead candidate SGX942 for the treatment of oral mucositis induced by cancer treatments.

Dr. Sonis is a Clinical Professor of Oral Medicine at Harvard School of Dental Medicine and Senior Surgeon and Chief, Divisions of Oral Medicine at Brigham and Women's Hospital and the Dana-Farber Cancer Institute, and Chief Scientific Officer of BioModels, LLC. Dr. Sonis is a veteran in the field of oral mucositis induced by chemoradiation therapy (CRT).

According to Dr. Sonis, significant mucositis occurs in about 450,000 patients per year in the US including patients who receive standard chemotherapy regimens (breast, colorectal cancer, lung cancer, etc.). Consequently, chemotherapy dose-de-escalation is a current strategy.

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.

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. Palifermin was studied in this population and did impact incidence (modestly), but has not been approved probably because of concern on tumor effect. 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.

Palifermin(Kepivance) is approved for the prevention of mucositis in patients with hematological malignancies who receive conditioning regimens prior to transplant. Its use is limited, probably because of cost ($10k for a 6 dose course) and because it has to be given prophylactically (the incidence of severe OM in this group is about 40% so one treats 10 when only 4 actually benefits).

The pathobiology of OM is more complex than was originally thought. The condition evolves through a sequence of biological events that culminate with destruction of epithelial stem cells that are critical to epithelial tissue renewal. It appears that the innate immune response is a key player in the initiation of the destructive process. Thus, by effectively mitigating this event, as proposed for SGX942, the process is delayed or prevented. Additional studies will be needed to conclusively demonstrate this MOA.

Given the proposed MOA, SGX942 has the potential to favorably impact other epithelial toxicities associated with radiotherapy including dermatitis, esophagitis and proctitis. In theory, it could also favorably impact other tissue-based injury such as fibrosis and, perhaps, systemic complications such as fatigue.

Dr. Sonis further pointed out that the annual global market for mucositis has been estimated to be between $750MM and $1.2B and is growing dramatically with the growing cancer market.

The interview with Dr. Sonis further convinces us that Soligenix SGX-942 has the potential to become the choice of agent for the management of OM resulted from HNC.

Update on SGX301 for CTCL

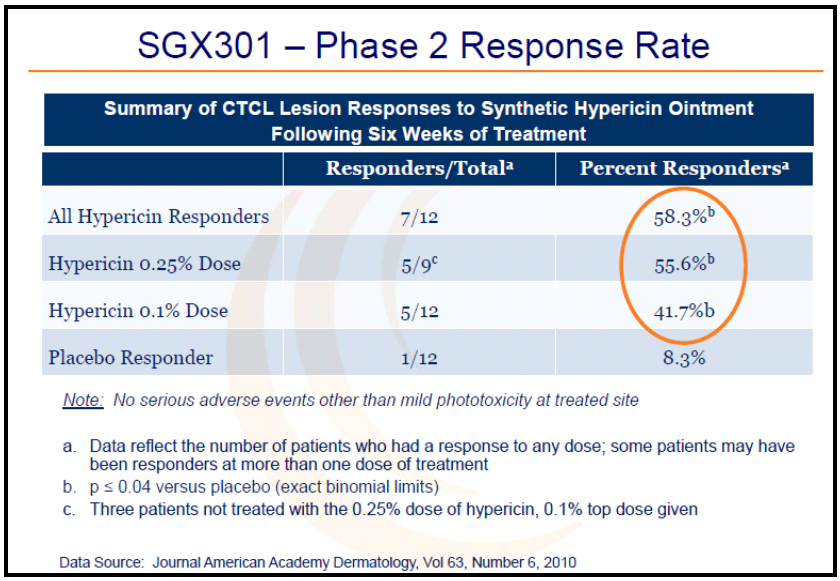
On December 14, 2015, Soligenix announced the initiation of its much anticipated **pivotal Phase III** trial of SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL).

Background

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.

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 ($p < 0.04$).



The Pivotal Phase III Trial

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

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

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

- The trial will consist of three treatment cycles, each of 8 weeks duration.
- Treatments will be administered twice weekly for the first 6 weeks and treatment response will be determined at the end of Week 8.
- In the first treatment cycle, approximately 80 patients will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all patients will receive SGX301 treatment of their

index lesions and in the third (open-label) cycle all patients will receive SGX301 treatment of all their lesions;

- Subjects will be followed for an additional 6 months after the completion of treatment;
- The primary clinical efficacy endpoint is treatment response assessed using the CAILS (Composite Assessment of Index Lesion Severity) score evaluating the three worst index lesions at the end of Cycle 1 (Week 8).
- Other secondary measures will assess treatment response (including duration), degree of improvement, time to relapse and safety.

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

The Implication

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

We think the initiation of the Phase III trial marks an important milestone in the development of SGX301 as a treatment for CTCL. We believe the collaboration with NORD and CLF will greatly accelerate the patient enrollment process and therefore accelerate the completion of the Phase III trial.

We estimate SGX301 could be approved by the FDA in late 2017 or early 2018 if data from the Phase III trial are positive.

SGX301 has received **orphan drug** and **fast track** from the FDA for the treatment of CTCL. It also received orphan drug designation in EU for CTCL.

CTCL is a class of non-Hodgkin's lymphoma (NHL). It is estimated that CTCL affects over 20,000 individuals in the US, with approximately 2,800 new cases seen annually.

With CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no cure for CTCL.

We welcome the acquisition of late stage candidate SGX301, and the collaboration with NORD and CLF to advance the candidate, which, we think, will have positive impact for the company's operations and valuation. Soligenix becomes a **late development stage** biotech company through the acquisition of SGX301, which is highly synergistic with the company's existing development pipeline.

SGX301 may also be developed for other indications such as **psoriasis**, which further expands the company's pipeline. Psoriasis is a common autoimmune disease that affects over 7 million adults in the US. Photodynamic therapy is a frequently used initial therapy for psoriasis, despite the need for ultraviolet light exposure and its attendant risk of melanoma and non-melanoma skin cancer.

PROJECTED INCOME STATEMENT

	2015					2016					2017	2018	2019
$ 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	$0.8	$1.1	$3.9	$3.0	$8.8	$2.6	$3.2	$2.5	$2.5	$10.8	$9.0	$9.0	$9.0
YOY Growth	*-10.4%*	*-22.5%*	*39.2%*	*54.3%*	*24.5%*	*222.3%*	*187.3%*	*-35.6%*	*-15.9%*	*23.1%*	*-16.6%*	*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	$2.0	$15.0	$35.0
YOY Growth	-	-	-	-	-					-	-	-	-
Total Revenues	**$0.8**	**$1.1**	**$3.9**	**$3.0**	**$8.8**	**$2.6**	**$3.2**	**$2.5**	**$2.5**	**$10.8**	**$11.0**	**$24.0**	**$44.0**
YOY Growth	*-10.4%*	*-22.5%*	*39.2%*	*54.3%*	*24.5%*	*222.3%*	*187.3%*	*-35.6%*	*-15.9%*	*23.1%*	*1.9%*	*118.2%*	*83.3%*
Cost of Revenue	$0.5	$0.8	$3.1	$2.5	$6.9	$2.2	$2.3	$2.1	$2.1	$8.8	$9.0	$6.0	$8.0
Gross Income	**$0.3**	**$0.3**	**$0.8**	**$0.5**	**$1.9**	**$0.4**	**$0.8**	**$0.4**	**$0.4**	**$2.0**	**$2.0**	**$18.0**	**$36.0**
Gross Margin	*35.4%*	*25.7%*	*21.4%*	*16.3%*	*21.5%*	*15.2%*	*25.9%*	*16.0%*	*16.0%*	*18.7%*	*18.0%*	*75.0%*	*81.8%*
R&D	$1.0	$1.4	$1.3	$1.7	$5.4	$2.0	$0.8	$2.5	$3.0	$8.3	$7.0	$7.5	$8.0
% R&D	*126.2%*	*131.2%*	*32.5%*	*56.1%*	*61.6%*	*76.0%*	*26.2%*	*100.0%*	*120.0%*	*77.2%*	*63.6%*	*31.3%*	*18.2%*
SG&A	$0.8	$0.9	$0.8	$1.1	$3.6	$1.1	$1.0	$1.2	$1.2	$4.5	$7.5	$10.0	$13.0
% SG&A	*100.1%*	*79.6%*	*21.6%*	*35.8%*	*41.0%*	*41.8%*	*31.6%*	*48.0%*	*48.0%*	*41.7%*	*68.2%*	*41.7%*	*29.5%*
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	**($1.6)**	**($2.0)**	**($1.3)**	**($2.2)**	**($7.1)**	**($2.7)**	**($1.0)**	**($3.3)**	**($3.8)**	**($10.8)**	**($12.5)**	**$0.5**	**$15.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	($3.0)	($1.9)	$4.0	($0.3)	$1.2	$0.8	$0.9	$0.0	$0.0	$1.7	$0.0	$0.0	$0.0
Pre-Tax Income	**($4.6)**	**($4.0)**	**$2.8**	**($2.5)**	**($8.3)**	**($1.9)**	**($0.1)**	**($3.3)**	**($3.8)**	**($9.1)**	**($12.5)**	**$0.5**	**$15.0**
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%*	*19.2%*	*5.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($4.6)**	**($4.0)**	**$2.8**	**($2.1)**	**($7.8)**	**($1.9)**	**($0.1)**	**($3.3)**	**($3.8)**	**($9.1)**	**($12.5)**	**$0.5**	**$15.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*2.4*	*2.6*	*2.8*	*2.6*	*2.6*	*3.3*	*3.3*	*3.8*	*4.0*	*3.6*	*5.0*	*6.0*	*7.5*
Reported EPS	**($1.87)**	**($1.55)**	**$0.98**	**($0.80)**	**($3.00)**	**($0.60)**	**($0.03)**	**($0.87)**	**($0.95)**	**($2.55)**	**($2.50)**	**$0.08**	**$2.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One-time charge	$3.01	$1.94	($4.04)	$0.30	$1.21	($0.76)	$0.00	$0.00	$0.00	($0.76)	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.6)**	**($2.0)**	**($1.3)**	**($1.8)**	**($6.6)**	**($2.7)**	**($0.1)**	**($3.3)**	**($3.8)**	**($9.9)**	**($12.5)**	**$0.5**	**$15.0**
Non GAAP EPS	**($0.64)**	**($0.79)**	**($0.45)**	**($0.68)**	**($2.54)**	**($0.83)**	**($0.03)**	**($0.87)**	**($0.95)**	**($2.76)**	**($2.50)**	**$0.08**	**$2.00**

Source: Company filings and Zacks estimates

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