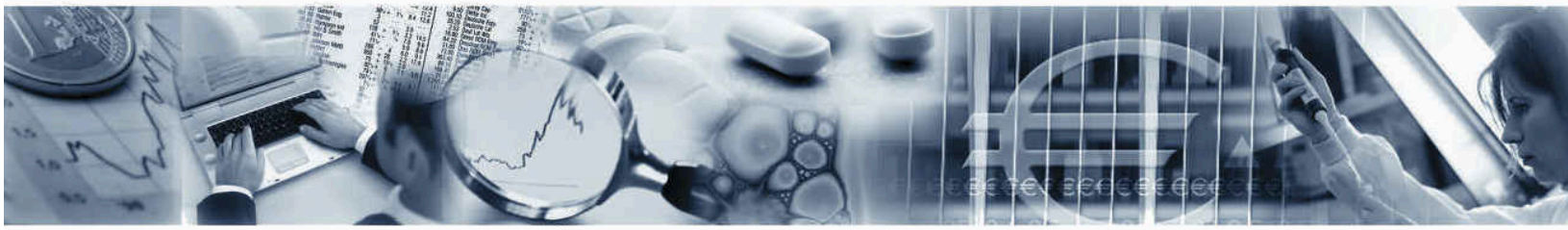

Research Note

Soligenix Inc.

2018: Focus on Pivotal Trials

Chief Research Analyst

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Name:	**Soligenix**
Country:	**United States**
Price:	**USD 2.02**
ISIN Code:	**US8342233074**
Reuters Code:	**SNGX**
Market Cap (USD m):	**18.0**
EV (EUR m):	**10.0**
Cash & cash eq. (USD m):	**8.0**
Shares outstanding (m):	**8.73**
Volume:	**67,240**
Free float:	**100%**
52-week Range:	**1.74-5.08**

USD million	2015A	2016A	2017E
Total Revenues	8.8	10.4	6.0
Net (Loss)/Profit	(7.8)	(3.4)	(6.0)
Net (loss)/profit ps	(3.00)	(1.34)	(0.69)
R&D costs	5.4	4.3	3.0
Cash increase/(decrease)	(0.6)	3.9	(0.8)
Cash and marketable sec.	4.9	8.8	8.0

- Soligenix is a late-stage biopharmaceutical company that is focused on the development and commercialization of products to treat rare diseases that have a high unmet medical need. The Company operates through two segments: BioTherapeutics and Vaccines/BioDefense.

- The Company's BioTherapeutics segment is developing a photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL), a first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

- Its Vaccines/BioDefense segment includes active development programs for RiVax®, its ricin toxin vaccine candidate, OrbeShield®, its GI acute radiation syndrome (GI ARS) therapeutic candidate, and SGX943, its therapeutic candidate for antibiotic resistant and emerging infectious disease, including melioidosis. The development of its vaccine programs incorporates the use of its proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA).

- Soligenix has a broad late stage pipeline in rare diseases, of which three programs currently are in Phase III: SGX301 in CTCL, SGX942 in Oral mucositis in head and neck cancer and SGX203 in Pediatric Crohn's disease. Each of these programs offers significant market potential of up to USD 1 billion in total annually.

- The company's cash position at the end of 2017 was USD 10 million which should be sufficient to carry out the further development of its pipeline into 2019H1. In addition, the company continues to actively pursue government grants and contracts across its entire biodefense and biotherapeutics pipeline. In 2017, Soligenix received more than USD 8.6 million in non-dilutive awards.

- **Based on NPV calculations, we believe that Soligenix is substantially undervalued at the current share price of USD 2.05. Using our valuation model and taking into account the future revenues from its late stage programs, the company's current total value should be USD 100-150 million, or USD 11.50-17.00 per share**

Company Profile

Soligenix is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The company has two divisions: BioTherapeutics and Vaccines/BioDefense.

The BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), its first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

The Vaccines/BioDefense divisio includes active development programs for RiVax®, the company's ricin toxin vaccine candidate, OrbeShield®, its GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, Soligenix' melioidosis therapeutic candidate. The development of the vaccine programs currently is supported by the company's proprietary heat stabilization technology, known as ThermoVax®, under existing and ongoing government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), Soligenix attempts to advance the development of RiVax® to protect against exposure to ricin toxin. With funds received from governmental contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID, Soligenix has advanced the development of OrbeShield® for the treatment of GI ARS.

Business Strategy

The Company intends to leverage its R&D capabilities to efficiently expand its pipeline to indications for which it believes its products have therapeutic potential. Its goals are as follows:

- Complete enrolment and report the results of its pivotal Phase III of SGX301 for the treatment of CTCL
- Complete enrolment and report the results of its pivotal Phase III protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients
- Initiate a pivotal Phase III trial of SGX203 in for the treatment of pediatric Crohn's disease contingent upon additional funding support
- Continue development of RiVax® in combination with its ThermoVax®, potentially qualifying for a priority review voucher and/or a procurement contract
- Further the development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support
- Continue to apply for and secure additional government funding for each program in BioTherapeutics and Vaccines/BioDefense
- Acquire or in-license new clinical stage compounds for development
- Continue building development and commercial partnerships

Technology Platforms

For the development of its clinical programs, Soligenix makes use of various technology platforms:

- IDR Technology for SGX942
- Photodynamic (PDT) therapy for SGX301
- Heat Stabilization Technology ThermoVax®

Innate Defense Regulator (IDR) Technology

Innate Defense Regulators (IDRs) are a new class of compounds with a novel mechanism of action. These compounds modulate the innate immune system by impacting a key intracellular checkpoint in the innate immune response. Innate immunity is an often under-appreciated aspect of the immune system. While the adaptive immune system can respond to specific insults by generating antibodies and targeted T-cells, the innate immune system is both more general and faster. The innate immune system is the first line of defense and responds to infection and / or tissue damage. In addition to fighting off infection and healing tissue, it also mounts an inflammatory response. The innate immune system is a highly integrated system of cells protecting us from pathogens at all body surfaces that interface with the external environment: skin, mouth, gastrointestinal tract and lung. Innate immunity is dependent on rapidly sensing infection or damage and responding quickly with both inflammation and host repair or anti-infective functions. When excessive activation of innate immunity causes inflammation, modulation of the activated innate immune system can re-direct the system to decrease inflammatory responses and increase the anti-infective or healing responses. The innate immune system responds quickly by sensing nonspecific molecules released by the process of infection and damage through its Toll-like receptors and associated receptors. One of the key molecules in transmission of the sensing information is an adaptor protein called sequestosome-1 or p62. By interacting with p62, a "signal integrator" in innate defense signaling pathways present in most cell types, IDRs direct the innate immune response to modulate inflammation and increase anti-infective and tissue-healing activities.

The Company's lead IDR, Dusquetide (under the drug product name SGX942), is being evaluated in a pivotal Phase III clinical study in oral mucositis in head and neck cancer patients, having successfully demonstrated efficacy in a recently completed Phase II study in the same patient population. The combination of chemotherapy and radiation treatment for the head and

neck cancer causes damage to the oral cavity, which results in painful ulcers which can inhibit speaking, swallowing, eating and even drinking. The mucositis can be so severe that patients halt their life-saving tumour treatment. Innate immunity has a strong impact in mucositis, and the inflammation associated with the innate immune response to tissue damage caused by the chemotherapy and radiation is believed to exacerbate the damage caused by the tumour treatment. Treatment with SGX942 reduced the duration of severe oral mucositis in this patient population. Severe oral mucositis defined as pain so bad patients can no longer eat and/or drink, potentially causing malnourishment, dehydration and discontinuation of cancer treatment. At the same time, the incidence of infection was also decreased. These results demonstrated that the IDR technology translates well from preclinical animal models to the clinical setting.

Other indications for the IDR technology include the treatment of bacterial infections. While antibiotics directly target the bacteria – encouraging bacterial cell death through a variety of mechanisms, IDRs do not interact with the bacteria. Rather, they augment the host response to the bacteria, enhancing the normal responses of the innate immune system. Because IDRs do not target the bacteria directly, it doesn't matter how the bacteria behave, if they are intracellular or extracellular, have developed adaptations to antibiotics or not, have gram-positive or gram-negative membranes. Thus, IDRs are very broad spectrum. In contrast, antibiotics are usually directed to only a subset of bacteria, depending on their specific mechanism.

Photodynamic Therapy (PDT) in cancer

Photosensitizers in photodynamic therapy (PDT) have been used to treat skin disease for centuries. PDT is a cancer treatment that requires the interaction of a photosensitizer (PS), light and oxygen. A PS is characterised as a non-toxic drug or dye which is excited using light at a specific wavelength. The excited PS will react with oxygen present in biological tissue to produce reactive oxygen species (ROS) that destroys cancerous cells by inducing cell death. The PS uptake by cancerous tissue in combination with localised light delivery makes PDT an effective oncology

treatment that prevents damage to surrounding normal healthy tissue. To date, most PSs for PDT have been chemically synthesized and modified to satisfy the demands for an ideal PS. However, a naturally occurring red plant pigment (Hypericin) has drawn increased interest as a new generation PDT drug. It is known to have high quantum yields (therefore very efficient photoactivation), tumor selectivity and low production costs. Other beneficial properties of hypericin include low photobleaching, low cytotoxicity in the absence of light and no mutagenicity. SGX301 is a novel photodynamic therapy that combines a highly purified synthetic hypericin, a photosensitizer that is applied to the cancerous skin lesions and activated using a brief fluorescent light treatment. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed offf-label, unapproved use of DNA-damaging chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet exposure, such as psoralen activated with ultra-violet A light (referred to as PUVA) .

Heat Stabilization Technology ThermoVax®

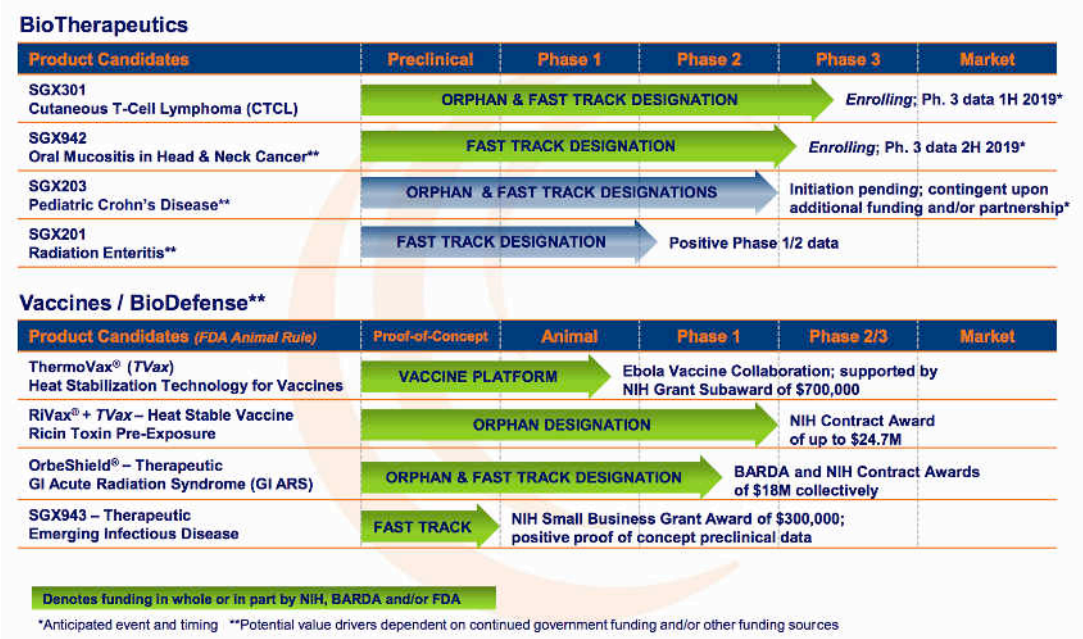
Soligenix's proprietary thermostability technology ThermoVax® is designed to eliminate the cold chain production, distribution and storage logistics required for most vaccines. It is a novel method of rendering aluminum salt, Alum, adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. The World Health Organization (WHO) reports that as much as 50% of all vaccines around the world are wasted due to thermostability issues. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. The savings

realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also further facilitate the use of these vaccines in the lesser developed parts of the world. For vaccines that are intended for long-term stockpiling, such as for use in biodefense or in pandemic situations, the utilization of ThermoVax® has the potential to facilitate easier storage and distribution of Strategic National Stockpile vaccines in emergency situations. The underlying ThermoVax® technology has been developed by Drs. John Carpenter and Theodore Randolph at the University of Colorado. In addition to its lead vaccine program, RiVax®, that uses this platform technology, the Company is also participating in a NIAID grant with the University of Hawaii and Hawaii Biotech to deverlop a thermostabilized Ebola vaccine.

Pipeline: Focus on Rare Diseases

Soligenix has a broad late stage pipeline in rare diseases, of which three programs currently are in Phase III:

- SGX301 in Cutaneous T-cell lymphoma: Currently enrolling, with results expected in 2019H1
- SGX942 in Oral mucositis in Head&Neck cancer: Currently enrolling, with results expected in 2019H2
- SGX203 in Pediatric Crohn's disease: a pivotal study targeted to begin in 2018H2, contingent upon additional funding and/or partnership.



Source: Soligenix

BioTherapeutics

SGX301: Cutaneous T-Cell Lymphoma

SGX301 is a novel photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of *Hypericum* plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process to form a highly potent and purified form, not extracted from plants. Importantly, synthetic hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA or UVB light result in serious adverse effects including secondary potentially fatal skin cancers.

Topical, synthetic hypericin has demonstrated safety in a Phase I clinical study in healthy volunteers. In a Phase II, placebo-controlled, clinical study in patients with CTCL, the drug was safe, well tolerated, and effective in ameliorating the skin lesions. These clinical data fully support advancing this therapy to a pivotal Phase III clinical trial in CTCL.

Combined with photoactivation, synthetic hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration-dependent as well as a light dose-dependent fashion. Hypericin is one of the most efficient known generators of singlet oxygen, the key intermediate for phototherapy. The generation of singlet oxygen induces localized necrosis and apoptosis. The use of topical synthetic hypericin coupled with directed visible light results in generation of singlet oxygen only at the required site. The use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase II clinical study in CTCL, 58.3% of patients receiving SGX301 while only 8.3% of those receiving placebo experienced a significant response, a statistically significant difference ($p < 0.04$). SGX301 has received Orphan

Drug designation as well as Fast Track designation from the FDA. In addition, SGX301 has been granted Orphan Drug designation from the EMA and Promising Innovative Medicine (PIM) designation in the UK by the MHRA for the treatment of CTCL.

Soligenix initiated a pivotal Phase III clinical study of SGX301 for the treatment of CTCL during December 2016 and is actively enrolling patients. The Phase III protocol is a highly powered, double-blind, randomized, placebo-controlled, multicenter trial and seeking to enroll approximately 120 evaluable subjects. The trial consists of three treatment cycles, each of eight weeks duration. Treatments will be administered twice weekly for the first six weeks and treatment response will be determined at the end of the eighth week. In the first treatment cycle, approximately 80 subjects will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all subjects will receive SGX301 treatment of their index lesions, and in the optional third cycle all subjects will receive SGX301 treatment of all of their lesions. Subjects will be followed for an additional six months after the completion of treatment. The primary efficacy endpoint will be assessed on the percentage of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a partial or complete response of the treated lesions, defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Other secondary measures will assess treatment response, including duration, degree of improvement, time to relapse and safety.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with NHL. We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the US, with approximately 2,800 new cases seen annually.

SGX942 (dusquetide): Oral mucositis in Head & Neck Cancer

SGX942 is an Innate Defense Regulator ("IDR") that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. SGX942 is based on a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action, simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. SGX942 is Soligenix' product candidate containing the company's IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, the company received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA. In addition, SGX942 has been granted Promising Innovative Medicine (PIM) designation in the UK by the MHRA for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy.

In December 2013, Soligenix initiated a Phase II clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients. Enrollment was completed in this trial in 2015H2 and in December 2015 the company released positive preliminary results. In this Phase II proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. In addition to

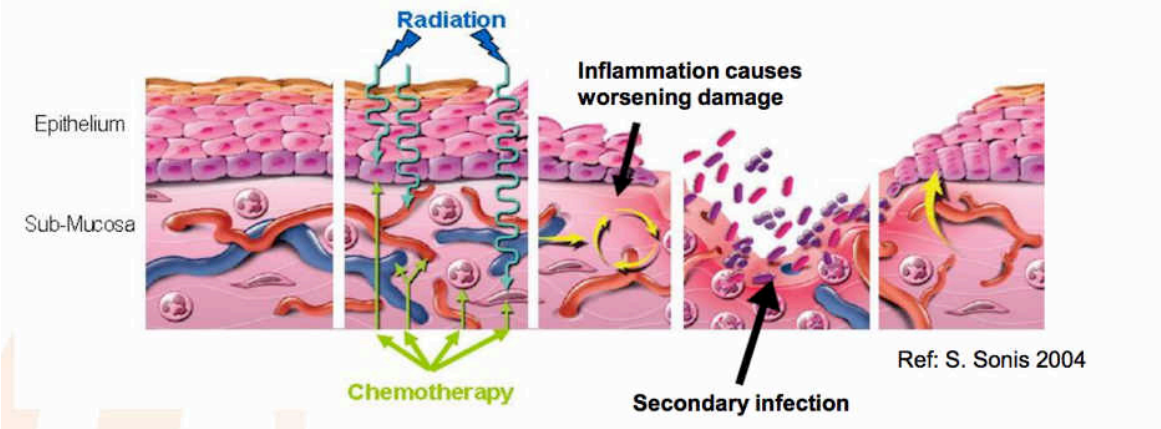
identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of "complete response" of tumor at the one month follow up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models. SGX942 was found to be 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 (12 month) follow-up data was also consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results 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 1.5mg/kg treatment group had a 40% decrease in the use of opioids at the later stage of the treatment phase of the trial, when oral mucositis is usually most severe and expected to increase paid medication use. This was in contrast to the placebo group, which demonstrated a 10% increase in use of opioids over this same period. Data from this Phase II trial was published online in the Journal of Biotechnology. The publication also delineates the supportive nonclinical data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets.

On September 9, 2016, Soligenix and SciClone Pharmaceuticals entered into an exclusive license agreement, pursuant to which Soligenix granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in China. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in China,

having access to data generated by Soligenix. In exchange for exclusive rights, SciClone made a USD 3 million investment in Soligenix at a 35% premium to market. SciClone will pay Soligenix royalties on net sales, and Soligenix will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

Soligenix has received agreement from FDA on the design of a pivotal Phase III protocol for SGX942 in the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. Additionally, Soligenix has received positive Scientific Advice from the EMA for the development of SGX942 as a treatment for oral mucositis in patients with head and neck cancer. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase III pivotal study, if successful, in conjunction with the Phase II dose-ranging study, is generally considered sufficient to support a marketing authorization application ("MAA") to the EMA for potential licensure in Europe.

Based upon a review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, we estimate that oral mucositis is a subpopulation of approximately 90,000 patients in the US, with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.



SGX203: Pediatric Crohn's Disease

SGX203 is a two tablet delivery system of beclomethasone dipropionate (BDP) specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 orphan drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease. The potential worldwide market for oral BDP is estimated to be in excess of USD 500 million for all applications, including the treatment of pediatric Crohn's disease. This potential market information is a forward-looking statement.

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

ThermoVax®: Thermostability Technology

ThermoVax® is a novel method of rendering aluminum salt, (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax® lies in its potential ability to eliminate the need for cold chain production, transportation, and storage for Alum adjuvanted vaccines. ThermoVax® development was supported pursuant to a USD 9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax®) and anthrax (VeloThrax™) vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with Soligenix's aluminum-adjuvanted ricin toxin vaccine, RiVax® and its aluminum-adjuvanted anthrax vaccine, VeloThrax™. Further proof of concept data has also been generated with human papillomavirus (HPV) and Ebola vaccine antigens.

RiVax®: Ricin Toxin Vaccine

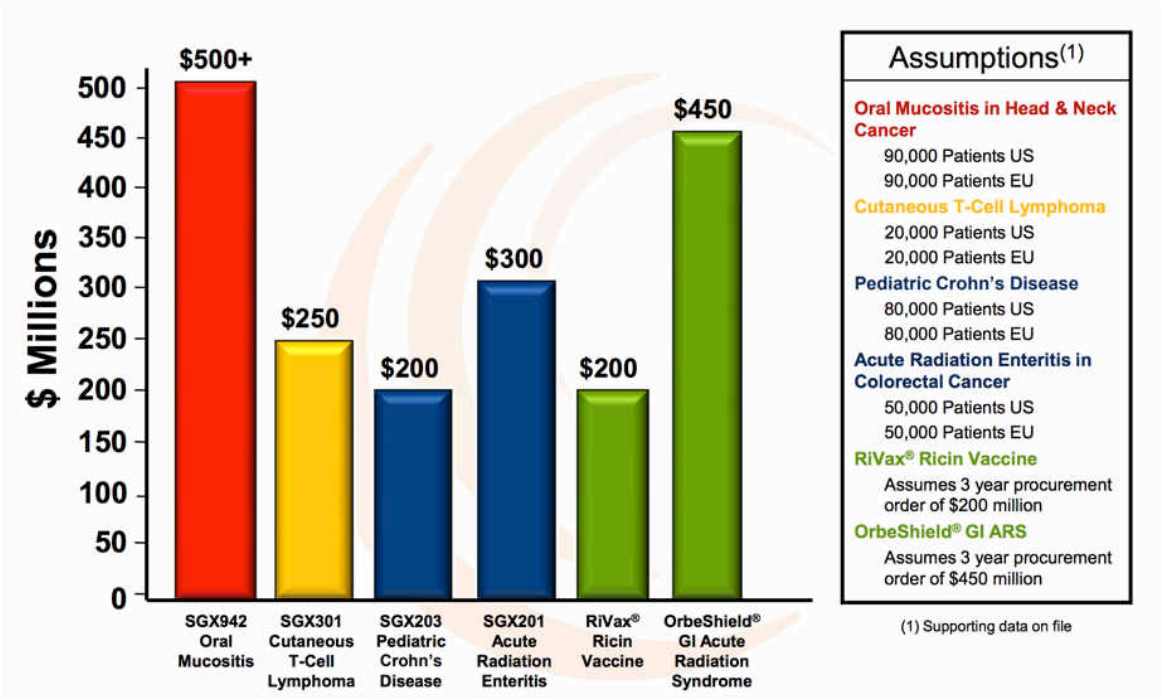
RiVax is a proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved would be the first ricin vaccine. The immunogen in RiVax® induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax® has demonstrated statistically significant ($p<0.0001$) preclinical survival results in a lethal aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects

rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA March 24, 2015), and has also been shown to be well tolerated and immunogenic in two Phase I clinical trials in healthy volunteers. Results of the first Phase I human trial of RiVax® established that the immunogen was safe and induced antibodies that may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The second trial, which was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center ("UTSW"), evaluated a more potent formulation of RiVax® that contained an aluminum adjuvant (Alum). The results of the Phase Ib study indicated that Alum adjuvanted RiVax® was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax®. Soligenix has adapted the original manufacturing process for the immunogen contained in RiVax® for thermostability and large scale manufacturing and are further establishing correlates of the human immune response in non-human primates. Soligenix has entered into a collaboration with IDT Biologika GmbH to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. The company has also initiated a development agreement with Emergent BioSolutions to implement a commercially viable, scalable production technology for the RiVax® drug substance protein antigen.

In September 2014, Soligenix was awarded a contract with the NIH for the development of RiVax® that provides up to an additional USD 24.7 million of funding in the aggregate if all options are exercised. The development agreements with Emergent BioSolutions and IDT are specifically funded under this NIH contract, as well as a Phase 2 clinical study of the thermostabilized RiVax formulation. RiVax® has been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication.

Assuming development efforts are successful for RiVax®, the company believes potential government procurement contract(s) could reach USD 200 million. In addition, RiVax® approval may also qualify Soligenix for a priority review voucher (PRV), which enables accelerated review and is transferable. PRV sales have ranged from USD125 to 350 million in recent years.

Significant Global Market Potential for Soligenix' rare disease programs



Source: Soligenix

Near Term Milestones

In the coming 12 months we expect a number of important mile stones that can drive the stock price upwards. These are:

- 2018H1: Phase I/II start Human safety in RiVax®
- 2018H2: Phase III interim analysis in CTCL with SGX301
- 2018H2: Start Phase III SGX203 in Pediatric Crohn's Disease
- 2019H1: Phase III data CTCL with SGX301
- 2019H1 Phase III interim analysis in Oral Mucositis with SGX942
- 2019H1: Phase I/II data RiVax®
- 2019H2: NDA submission SGX301 in CTCL
- 2019H2: Phase III data SGX942 in Oral Mucositis

Analyst: Marcel Wijma MSc
Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.