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## Overview

Soligenix, Inc. is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need.

Through its BioTherapeutics Division, Soligenix is developing three drug candidates: SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL), SGX942 (dusquetide) for the treatment of oral mucositis in head and neck cancer, and beclomethasone 17,21-dipropionate or BDP (a potent, locally-acting corticosteroid) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation, such as pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Through its Vaccines/BioDefense Division, Soligenix is developing biodefense medical countermeasures (MCMs) pursuant to the Biomedical Advanced Research and Development Authority (BARDA) Strategic Plan of 2011-2016 and the National Institute of Allergy and Infectious Diseases (NIAID) Biodefense Strategic Plan. Soligenix's biodefense candidates include a heat stable recombinant subunit vaccine called RiVax<sup>®</sup>, designed to protect against the lethal effects of exposure to ricin toxin; OrbeShield<sup>®</sup>, an oral therapeutic for the treatment of GI acute radiation syndrome (GI ARS) and SGX943 for the treatment of emerging and antibiotic resistant infectious disease. The RiVax<sup>®</sup> development program also uses ThermoVax<sup>®</sup>, a proprietary vaccine heat stabilization platform technology.

## Investment Highlights

- Diversified product portfolio spanning BioTherapeutics and Vaccines/BioDefense
- Experienced management team and Board of Directors
- Multiple orphan (rare) disease and fast-track development programs with significant market potential
- Advanced clinical development, including **SGX301** for CTCL (Phase 3), **SGX203** for pediatric Crohn's disease (Phase 3) and **SGX942** for oral mucositis (Phase 3)
- Significant non-dilutive contract/grant funding provided by the government, including
  - ◊ National Institute of Allergy and Infectious Diseases (NIAID) contract award of up to \$24.7M supporting RiVax<sup>®</sup> development
- Exclusive collaborations with biotech, academia and government agencies
- Potential to be granted biodefense Priority Review Voucher, if FDA approval of MCM is obtained

### BioTherapeutics

- **SGX301** to treat CTCL, representing a market in excess of \$250M annually worldwide
- Dusquetide to treat innate immune disorders, including oral mucositis (**SGX942**) and bacterial infection, including antibiotic resistant infections, representing markets in excess of \$500M annually worldwide
- Oral BDP to treat inflammatory diseases of the GI tract, such as pediatric Crohn's disease (**SGX203**) and acute radiation enteritis (**SGX201**), representing markets in excess of \$200M annually worldwide

### Vaccines/BioDefense

- **ThermoVax<sup>®</sup>** — proprietary heat stabilization platform technology capable of eliminating cold chain production and storage concerns for aluminum-adjuvanted vaccines — proof of concept demonstrated
- **RiVax<sup>®</sup>** — a world leader in ricin toxin vaccine research with NIH funding in excess of \$30M to date which has demonstrated significant survival results in a non-human primate model of ricin exposure
- **OrbeShield<sup>®</sup>** — therapeutic utilizing novel delivery of oral BDP with BARDA and NIAID funding of in excess of \$18M to date which has demonstrated significant survival results in a canine model of GI ARS
- **SGX943** — therapeutic utilizing novel Innate Defense Regulator or IDR (dusquetide) which has demonstrated significant survival results in a mouse model of melioidosis and other gram-negative and gram-positive infections

[www.soligenix.com](http://www.soligenix.com)

Nasdaq: SNGX

**Stock Snapshot**  
as of 11/02/18

Market Cap:  
~ \$21 Million

Stock Price: \$1.18

Avg Daily Vol (3M):  
~ 311 K

Shares Outstanding:  
~ 17.7 Million

### Executive Team

Christopher J. Schaber, PhD  
*President & CEO*

Richard C. Straube, MD  
*Chief Medical Officer*

Oreola Donini, PhD  
*Chief Scientific Officer*

Karen Krumeich  
*Chief Financial Officer*

### Board of Directors

Christopher J. Schaber, PhD  
*Chairman, President & CEO*

Keith Brownlie, CPA  
*Director*

Gregg Lapointe, CPA  
*Director*

Mark Pearson  
*Director*

Robert J. Rubin, MD  
*Director*

Jerome Zeldis, MD, PhD  
*Director*

### General Contact

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**BioTherapeutics**

Product Candidates	Preclinical	Phase 1	Phase 2	Phase 3	Market
SGX301 Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION			Enrolling; Ph. 3 data 1Q 2020*	
SGX942 Oral Mucositis in Head & Neck Cancer**	FAST TRACK DESIGNATION			Enrolling; Ph. 3 data 2H 2019*	
SGX203 Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATIONS			Initiation contingent upon additional funding and/or partnership*	
SGX201 Radiation Enteritis**	FAST TRACK DESIGNATION		Initiation contingent upon additional funding and/or partnership*		

**Vaccines / BioDefense\*\***

Product Candidates (FDA Animal Rule)	Proof-of-Concept	Animal	Phase 1	Phase 2/3	Market
ThermoVax® (TVax) Heat Stabilization Technology for Vaccines	VACCINE PLATFORM		Ebola Vaccine Collaboration: supported by NIH Grant Subaward of \$700,000		
RiVax® + TVax – Heat Stable Vaccine Ricin Toxin Pre-Exposure	ORPHAN DESIGNATION			NIH Contract Award of up to \$24.7M	
OrbeShield® – Therapeutic GI Acute Radiation Syndrome (GI ARS)	ORPHAN & FAST TRACK DESIGNATION		BARDA and NIH Contract Awards of \$18M collectively		
SGX943 – Therapeutic Emerging Infectious Disease	FAST TRACK	NIH Small Business Grant Award of \$300,000; positive proof of concept preclinical data			

Denotes funding in whole or in part by NIH, BARDA and/or FDA

\*Anticipated event and timing \*\*Potential value drivers dependent on continued government funding and/or other funding sources

**BioTherapeutics**

SGX301 is a novel, first-in-class photodynamic therapy utilizing safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a potent photosensitizer which is topically applied to skin lesions and then activated by fluorescent light. Combined with photoactivation, 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 a published Phase 2 clinical study in CTCL, patients experienced a significant response with topical hypericin treatment as compared to placebo: 58.3% compared to 8.3% (p ≤ 0.04), respectively. A Phase 3 pivotal study in CTCL is actively enrolling patients following positive interim analysis.

Dusquetide is a novel, proprietary 5-amino acid IDR which binds to a pivotal protein regulator of the innate immune system known as sequestosome-1 (p62). IDR binding to p62 reduces inflammation associated with activation of innate immunity while simultaneously enhancing resolution of infection and tissue damage. Initial development is focused on the use of dusquetide (SGX942) in the treatment of oral mucositis (OM), which is associated with a dysregulated innate immune response. In a published Phase 2 clinical study in OM in head and neck cancer (HNC), patients experienced a 50% reduction in the median duration of severe OM from 18 days to 9 days, and an even more striking 67% reduction in the median duration of severe OM from 30 days to 10 days (p = 0.04) in those patients receiving the most aggressive chemoradiation. A Phase 3 pivotal study in OM in HNC is actively enrolling patients.

Oral BDP (beclomethasone 17,21-dipropionate) is a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. Oral BDP is being developed in a novel formulation consisting of two tablets; the first intended to release BDP in the proximal portions of the GI tract, and the second in the distal portions. Soligenix has initiated development of this proprietary formulation of oral BDP (SGX203) for the treatment of pediatric Crohn's disease. A Phase 3 pivotal study in pediatric Crohn's disease has been cleared through FDA.

**Vaccines/BioDefense**

The World Health Organization (WHO) reports that as much as 50% of all global vaccine doses are wasted because vaccines are not kept within required temperature ranges. Aluminum-adsorbed vaccines typically need to be maintained between 2 and 8 degrees Celsius and even brief excursions from this temperature range may adversely affect potency and efficacy. Elimination of the cold chain would generate significant savings in storage and distribution and enhance the utility of these vaccines. Soligenix's thermostability technology, ThermoVax®, is a novel, proprietary method of stabilizing aluminum salt adjuvanted vaccines so that they are stable at temperatures exceeding 40 degrees Celsius.

Soligenix is currently developing biodefense MCMs pursuant to the Project BioShield Act of 2004 and the BARDA Strategic Plan of 2011-2016 for repurposing and/or inclusion in the US government's Strategic National Stockpile. Its ricin toxin vaccine, RiVax®, which uses ThermoVax®, has demonstrated statistically significant survival results in a lethal aerosol exposure NHP model and positive Phase 1 clinical trial results demonstrating that the vaccine is safe and induces antibodies against ricin in humans. A contract award from NIAID (up to \$24.7M) is funding RiVax® development activities. Further, Soligenix is developing OrbeShield® (oral BDP) for the treatment of GI ARS, where it has demonstrated statistically significant survival results in a GI ARS canine model where dogs were exposed to lethal doses of irradiation and subsequently treated with OrbeShield®. Contract awards from both NIAID (~\$7M) and BARDA (~\$11M) have funded OrbeShield® development activities to date. In melioidosis, Soligenix has demonstrated statistically significant efficacy with SGX943, its novel IDR technology using dusquetide as the active ingredient, under a \$300,000 NIAID grant award.

Except for the historical information contained herein, the matters discussed in this document are forward-looking statements, the accuracy of which is subject to risks and uncertainties. Please refer to the Soligenix most recent Form 10-K and Form 10-Q for additional information about the company and related risks.