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Overview

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

Our Specialized BioTherapeutics business segment is developing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our 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).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs incorporates the use of our 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), the Biomedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA).

Investment Highlights

- Diversified product portfolio spanning Specialized BioTherapeutics and Public Health Solutions
- 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), **SGX942** for oral mucositis (Phase 3), and **SGX203** for pediatric Crohn's disease (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®** development
- Exclusive collaborations with biotech, academia and government agencies
- Potential to be granted biodefense Priority Review Voucher, if FDA approval of medical countermeasure (MCM) is obtained

Specialized 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

Public Health Solutions

- **ThermoVax®** — proprietary heat stabilization platform technology capable of eliminating cold chain production and storage concerns for aluminum-adjuvanted vaccines — proof of concept demonstrated
- **RiVax®** — 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®** — 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

Nasdaq: SNGX

Stock Snapshot *as of 01/08/20*

Market Cap: ~ $38 Million

Stock Price: $1.69

Avg Daily Vol (3M): ~ 134K

Shares Outstanding: ~ 22.3 Million

Executive Team

Christopher J. Schaber, PhD
President & CEO

Richard C. Straube, MD
Chief Medical Officer

Oreola Donini, PhD
Chief Scientific Officer

Jonathan Guarino, CPA
Chief Financial Officer

Board of Directors

Christopher J. Schaber, PhD
Chairman, President & CEO

Gregg Lapointe, CPA
Director

Diane Parks
Director

Mark Pearson
Director

Robert J. Rubin, MD
Director

Jerome Zeldis, MD, PhD
Director

General Contact

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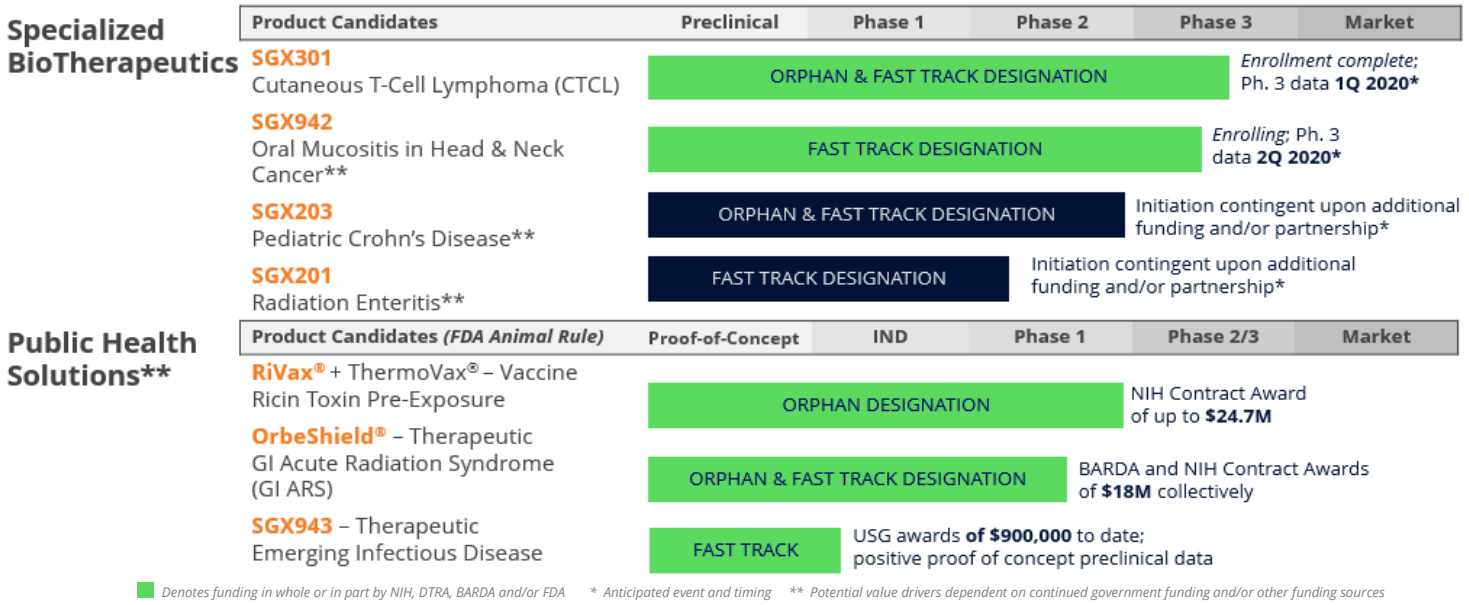
SOLIGENIX



Specialized 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% ($p \leq 0.04$), respectively. ***A Phase 3 pivotal study in CTCL has completed patient enrollment following positive interim analysis. Final top-line results expected 1Q 2020.***

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 following positive interim analysis. Final top-line results expected 2Q 2020.***

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.***

Public Health Solutions

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-adjuvanted 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. 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. 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 and is ***continuing to evaluate SGX943 against biodefense pathogens under a $600,000 subaward from the Defense Threat Reduction Agency.***

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.