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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 and commercializing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma. With a successful Phase 3 study completed, regulatory approval and commercialization for this product is being advanced initially in the US. Development programs in this business segment also include our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, 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 vaccine programs targeting both filoviruses (such as Marburg and Ebola) and coronaviruses (COVID-19; CiVax[™]). The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax[®]. We are also developing SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. 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), 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 ~\$21.2M supporting **RiVax[®]** development
 - ◊ NIAID grant award of ~\$1.5M supporting **CiVax[™]** and Ebola virus vaccine 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
- 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 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
- **CiVax[™]** — subunit protein vaccine with preclinical data supporting both immunogenicity and thermostability, specifically targeting SARS-CoV-2 (the cause of COVID-19)
- **Filovirus vaccines** — vaccines with demonstrated activity in non-human primates for ebola-like diseases, including Marburg virus for which there is no approved vaccine.
- **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 01/04/21

Market Cap:
~ \$41.4 Million

Stock Price: \$1.35

Avg Daily Vol (50D):
~ 1.2M

Shares Outstanding:
~ 30.6 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

Robert J. Rubin, MD
Director

Jerome Zeldis, MD, PhD
Director

General Contact

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Specialized BioTherapeutics

Product Candidates	Preclinical	Phase 1	Phase 2	Phase 3	Market
SGX301 Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION				Positive primary + Cycle 2 & 3 results
SGX942 Oral Mucositis in Head & Neck Cancer	FAST TRACK DESIGNATION				Evaluating full dataset; discussing with FDA/EMA*
SGX203 Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION			Initiation contingent upon additional funding and/or partnership*	
SGX201 Radiation Enteritis**	FAST TRACK DESIGNATION			Initiation contingent upon additional funding and/or partnership*	

Public Health Solutions**

Product Candidates (FDA Animal Rule)	Proof-of-Concept	IND	Phase 1	Phase 2/3	Market
RiVax® + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN & FAST TRACK DESIGNATION			NIH Contract Award of \$21.2M	
SGX943 – Therapeutic Emerging Infectious Disease	FAST TRACK	USG awards of \$900,000 to date; positive proof of concept preclinical data			
CiVax™ + ThermoVax® – Vaccine COVID-19	NIH Grant Award of \$1.5M ; positive proof of concept preclinical data				
Filovirus vaccines + ThermoVax® Ebola/Marburg	NIH Grant Subaward of \$700,000				

Denotes funding in whole or in part by NIH, DTRA, BARDA and/or FDA * Anticipated event and timing subject to COVID-19 disruption ** Potential value drivers dependent on continued government funding and/or other funding sources

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 visible 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 ($p \leq 0.04$) with topical hypericin treatment as compared to placebo. **A Phase 3 pivotal study in CTCL has resulted in a statistically significant improvement ($p=0.04$) in its primary endpoint** following 6 weeks of SGX301 treatment ("Cycle 1"). **Continued treatment up to 12 weeks results in a further improvement in response rate ($p \leq 0.0001$)** at the end of "Cycle 2", with similar results at the end of optional Cycle 3. **SGX301 treated both patches and plaques effectively (unlike other second-line treatments).** SGX301 was well-tolerated throughout the study. **Soligenix is advancing towards regulatory approval and commercialization of SGX301 in the U.S.**, where the market potential exceeds \$75M annually. The total addressable global market is estimated at approximately \$250M.

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. A recently completed Phase 3 study confirmed biological activity in the per protocol population but did not achieve statistical significance in the intent to treat populations. Discussions regarding potential paths forward with this program may be undertaken upon further review of the data.

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-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. Soligenix's thermostability technology, ThermoVax®, is a novel, proprietary method of stabilizing vaccines so that they can be maintained at temperatures exceeding 40 degrees Celsius.

Soligenix is currently developing biodefense MCMs pursuant to the Project BioShield Act and the BARDA Strategic Plan 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 (~\$21.2M) is funding RiVax development activities.** The ThermoVax technology is also being applied to a filovirus vaccine with proven activity in primates against both Marburg virus and 2 variants of Ebola virus, and to a potential coronavirus vaccine, CiVax, to address COVID-19. **A contract grant from NIAID (~\$1.5M) is funding CiVax and ThermoVax development activities.** Soligenix has demonstrated statistically significant efficacy with SGX943, its novel IDR technology using dusquetide as the active ingredient, against melioidosis and is **continuing to evaluate SGX943 against biodefense pathogens under a \$600,000 subaward from DTRA.**