



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 HyBryte™ (SGX301 or synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). 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 worldwide market potential
- Regulatory approval and commercialization plans for **HyBryte™** for CTCL (successful Phase 3 study completed) are being pursued with NDA filing targeted H1 2022 and projected launch in 2023
 - ◊ US annual peak sales projected at >\$90M with a concentrated sales force of ~20 reps
- Significant non-dilutive contract / grant funding provided by the government, including
 - ◊ NIAID contract awards have totaled ~\$30M to date in support of **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

- **HyBryte™** to treat CTCL, representing a total addressable 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 non-human primate 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

www.soligenix.com

Nasdaq: SNGX

Stock Snapshot
as of 05/07/21

Market Cap:
~\$51.3 Million

Stock Price: \$1.28

Avg Daily Vol (50D):
~2.8M

Shares Outstanding:
~40.1 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
HyBryte™ 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 Awards of \$30M to date; positive preclinical and clinical data	
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 to date; positive preclinical data	
Filovirus vaccines + ThermoVax® Ebola/Marburg				NIH Grant Subaward of \$700,000 to date; positive preclinical data	

■ 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

HyBryte™ (SGX301) is a novel, first-in-class photodynamic therapy utilizing safe visible light for activation. The active ingredient in HyBryte™ 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. **A successful pivotal Phase 3 has been completed, demonstrating rapid onset of efficacy (within 6 weeks) and continued improvement with continued treatment**, achieving outcomes other therapies may require months-years to attain in 18 weeks, and similar efficacy against patches and plaques, where other treatments typically work on patches but not plaques. HyBryte™ was well-tolerated throughout the study, with a significantly improved adverse event rate compared to other second-line treatment options. Soligenix is advancing **towards regulatory approval and commercialization of HyBryte™ in the U.S.**, where peak annual U.S. sales projections exceed \$90M and the total addressable global market is estimated at approximately \$250M. As a chronic disease requiring repeat treatment with diagnosis and treatment governed by a targeted set of specialists at Centers of Excellence, the commercial footprint for HyBryte™ is expected to be highly concentrated. With its broad efficacy and excellent safety profile, HyBryte™ is expected to be a preferred treatment modality in a field characterized by treatments limited to second-line use due to their toxicity profiles.

Dusquetide is a novel, proprietary 5-amino acid IDR which 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 population. Discussions regarding potential paths forward with this program awaits further review of the follow-up 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; targeting both the proximal and distal portions of the GI tract. Soligenix has initiated development 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, adversely affecting both 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 non-human primate (NHP) model and positive Phase 1 clinical trial results demonstrating that the vaccine is safe and induces antibodies against ricin in humans. The ThermoVax® technology is also being applied to a filovirus vaccine with proven activity in NHPs 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.**