

## 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 moving toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin sodium) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator (IDR) technology, dusquetide for the treatment of inflammatory diseases, including (SGX942) oral mucositis in head and neck cancer, and (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, and vaccine programs targeting both filoviruses (such as Marburg [MarVax™] and Ebola [SuVax™]) and coronaviruses (COVID-19; CiVax™). 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 worldwide market potential in excess of \$2B annually worldwide
- Successful Phase 3 study of **HyBryte™** for CTCL completed, with plans to conduct a 2<sup>nd</sup> confirmatory Phase 3 trial, agreed to with EMA, while continuing discussions with FDA on potential modifications to the development path to adequately address their feedback
- Phase 2 study to be initiated with **SGX945** in Behçet's disease
- 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 up to 3 Priority Review Vouchers (PRVs), if FDA approval of medical countermeasures (MCMs) is obtained

### Specialized BioTherapeutics

- **HyBryte™** to treat CTCL, representing a total addressable global market >\$250M annually
- Synthetic hypericin (active ingredient in HyBryte™) to treat mild-to-moderate psoriasis (**SGX302**), representing a total addressable global market >\$1B annually
- Dusquetide to treat inflammatory diseases such as oral mucositis (**SGX942**) and Behçet's disease (**SGX945**), a total addressable global market >\$700M annually

### 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
- **SuVax™/MarVax™** — filovirus vaccines with demonstrated activity in NHPs for ebola-like diseases, including Marburg virus for which there is no approved vaccine

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

Nasdaq: **SNGX**

**Stock Snapshot**  
as of 04/26/24

**Market Cap:**  
~\$6.6 Million

**Stock Price:** \$0.42

**Avg Daily Vol (3M):**  
~2.7M

**Shares Outstanding:**  
~15.8 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

**Soligenix, Inc.**  
29 Emmons Drive  
Suite B-10  
Princeton, NJ 08540  
Phone: (609) 538-8200  
Fax: (609) 452-6467  
[info@soligenix.com](mailto:info@soligenix.com)

## Specialized BioTherapeutics

Product Candidates*	Preclinical	Phase 1	Phase 2	Phase 3	NDA Review	Market
<b>HyBryte™</b> ( <i>synthetic hypericin sodium</i> ) Cutaneous T-Cell Lymphoma (CTCL)	ORPHAN & FAST TRACK DESIGNATION				Positive Phase 3 study results; 2 <sup>nd</sup> Phase 3 study accepted by EMA; FDA discussions remain ongoing	
<b>SGX942</b> ( <i>dusquetide</i> ) Oral Mucositis in Head & Neck Cancer**	FAST TRACK DESIGNATION			2 <sup>nd</sup> Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX203</b> ( <i>beclomethasone dipropionate</i> ) Pediatric Crohn's Disease**	ORPHAN & FAST TRACK DESIGNATION			Phase 3 study contingent upon additional funding and/or partnership		
<b>SGX302</b> ( <i>synthetic hypericin sodium</i> ) Mild-to-Moderate Psoriasis				Positive proof-of-concept demonstrated in Phase 1/2 pilot study; Phase 2a study ongoing		
<b>SGX945</b> ( <i>dusquetide</i> ) Aphthous Ulcers in Behçet's Disease	FAST TRACK DESIGNATION			FDA IND and Phase 2a protocol clearance received		

## Public Health Solutions\*\*

Product Candidates (FDA Animal Rule)*	Proof-of-Concept	IND	Phase 1	Phase 2/3	BLA Review	Market
<b>RiVax®</b> + ThermoVax® – Vaccine Ricin Toxin Pre-Exposure	ORPHAN & FAST TRACK DESIGNATION			NIH Contract Awards of <b>\$30M</b> to date; positive preclinical and clinical data		
<b>SuVax™</b> / <b>MarVax™</b> + ThermoVax® – Filovirus Vaccines	ORPHAN			NIH Grant Subaward of <b>\$700,000</b> to date; positive preclinical data		
<b>CiVax™</b> + ThermoVax® – Vaccine COVID-19				NIH Grant Award of <b>\$1.5M</b> to date; positive preclinical data		

## Specialized BioTherapeutics

HyBryte™ 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 cancerous skin lesions and then activated by visible light. **A successful pivotal Phase 3 has been completed, demonstrating rapid onset of efficacy (within 6 weeks) and continued improvement with extended treatment through 18 weeks.** HyBryte™ achieved outcomes in 18 weeks that other therapies may require months-years to attain, and had similar efficacy against patches and plaques, where some other treatments typically work on patches but not plaques. HyBryte™ was well-tolerated throughout the study, with an improved adverse event rate compared to other second-line treatment options. Soligenix has agreement with the EMA on a confirmatory Phase 3 study design largely replicating the initial Phase 3 study, while discussions remain ongoing with the FDA on potential modifications to the development path to adequately address their feedback, to advance **towards regulatory approval and commercialization of HyBryte™ worldwide**, where peak the total addressable global market is estimated at approximately \$250M. **The second confirmatory Phase 3 study will be initiated in 2024.** With its broad efficacy and excellent safety profile, HyBryte™ is expected to be a preferred treatment modality in a field characterized by treatments limited due to their toxicity profiles. Based on its validated biologic activity, Soligenix has recently **expanded synthetic hypericin development into psoriasis (SGX302), with preliminary evidence of clinical success in an ongoing Phase 2a study with study results expected in the first half of 2025.**

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 reduction of oral aphthous ulcers (oral mucositis) in patients receiving chemoradiation therapy in the per protocol population but did not achieve statistical significance in the intent to treat population. Completed discussions with certain regulatory authorities indicate that a second Phase 3 study will be required. Continued development of dusquetide (SGX942) will be contingent upon partnership. The same mechanism of action is expected to be useful in Behçet's disease, an orphan indication characterized by chronic recurring mucocutaneous (oral, genital and skin) aphthous ulcers. **Soligenix will be initiating a Phase 2a study evaluating dusquetide (SGX945) in patients with Behçet's disease in 2024 with study results in the first half of 2025.**

Oral BDP (beclomethasone 17,21-dipropionate) is a highly potent, topically active corticosteroid that is being developed for the treatment of pediatric Crohn's disease (SGX203). **A Phase 3 pivotal study 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. **Current stability data supports at least 2 years storage at this high temperature.**

Soligenix is currently developing biodefense MCMs pursuant to the Project BioShield Act and the BARDA Strategic Plan for repurposing and / or inclusion in the U.S. 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-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 filovirus vaccines with proven activity in NHPs against both Marburg virus (MarVax™) and Sudan Ebola virus (SuVax™), and to a potential coronavirus vaccine, CiVax™, to address COVID-19. **A recent publication has demonstrated 100% protection with a bivalent (MarVax™/SuVax™) vaccine.**