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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 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, a confirmatory Phase 3 study is currently under discussion with FDA and EMA. 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 (SGX942 and SGX945) 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).

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 [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
- Product development plans for **HyBryte™** for CTCL (successful Phase 3 study completed and 2nd confirmatory trial being negotiated with FDA and EMA) are being pursued in the U.S. and Europe
  - ◊ U.S. 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 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
- Oral BDP to treat inflammatory diseases of the GI tract, such as pediatric Crohn's disease (**SGX203**), representing global markets >$200M 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**

**Nasdaq: SNGX**

### Stock Snapshot *as of 01/04/24*

**Market Cap: ~$9.6 Million**

**Stock Price: $0.91**

**Avg Daily Vol (3M): ~2.9M**

**Shares Outstanding: ~10.5 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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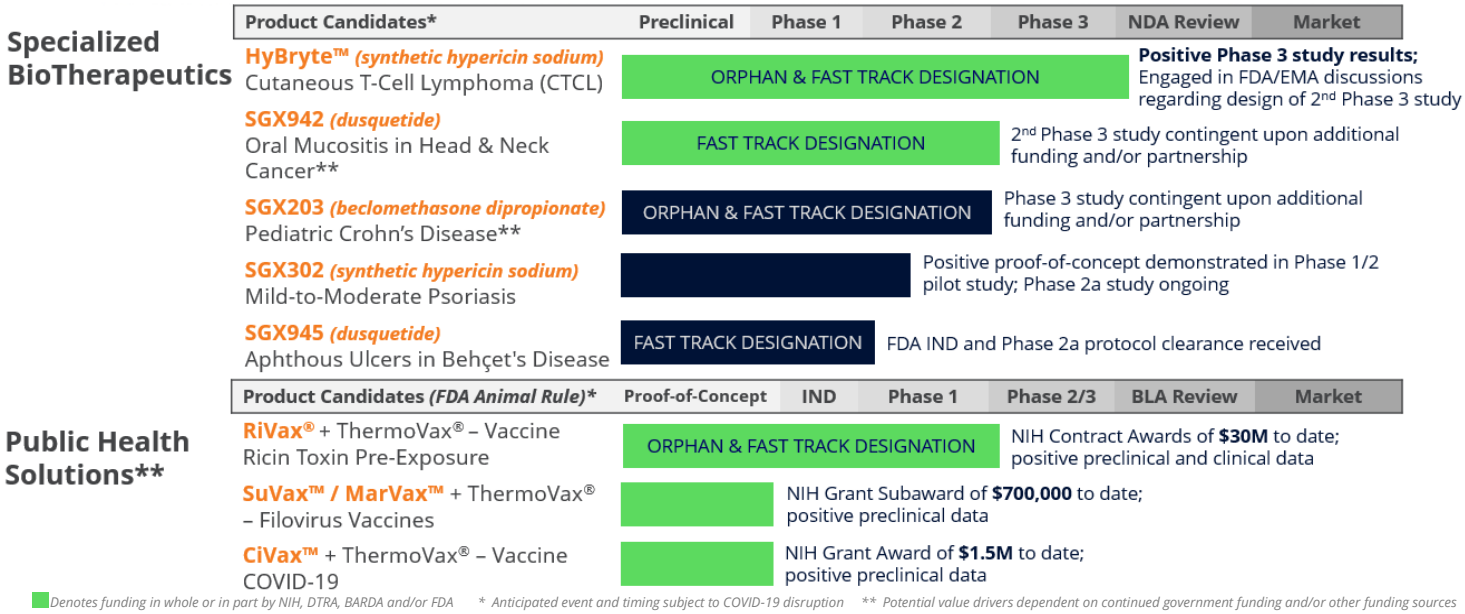
SOLIGENIX




*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 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.*** 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 is currently engaged in discussions with FDA and EMA to obtain agreement on a feasible design for a confirmatory Phase 3 trial that can be advanced ***towards regulatory approval and commercialization of HyBryte™ in the U.S. and Europe***, 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 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.***

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.

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.***