

Market Data

Soligenix, Inc. Nasdaq: SNGX

Fiscal Year	Dec. 31
Price	\$0.40
52-wk Range	\$0.37-\$2.00
Market Cap	\$6.3M
Shares Out.	15.8M
Float	\$6.3M
Avg. Vol (90-day)	2.8M
Revenue (ttm) at 12/31/23	\$0.8M
Cash (mrq) at 3/27/24	\$7.2M

Price & share data as of May 7, 2024

Auditor:

Cherry Bekaert LLP

Legal Counsel:

Duane Morris LLP

Transfer Agent:

Equiniti Trust Company

soligenix.com

Company 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. The Company's primary focus is on its Specialized BioTherapeutics business segment, which is responsible for the development of HyBryte™ (synthetic hypericin), a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). The Company has successfully completed a Phase 3 study for HyBryte™ and has reached agreement with the European Medicines Agency (EMA) on the key design components of a confirmatory Phase 3 pivotal study while discussions with the US Food & Drug Administration remain ongoing.

Additionally, Soligenix has expanded the clinical evaluation of synthetic hypericin (SGX302) into psoriasis, as well as developing proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention and treatment of gastrointestinal (GI) disorders characterized by severe inflammation. The Company is also developing a first-in-class innate defense regulator (IDR) technology, dusquetide, to treat inflammatory diseases, including oral mucositis in head and neck cancer (SGX942) and Behçet's disease (SGX945). Soligenix received FDA IND clearance in Q4 2023 for a Phase 2 trial of SGX945 (dusquetide) for the treatment of aphthous ulcers in Behçet's disease and "Fast Track" designation from the FDA in January 2024.

Soligenix's Public Health Solutions business segment is responsible for the development of a number of exciting new products designed to combat a variety of severe medical conditions, including RiVax®, a ricin toxin vaccine candidate that will combat ricin poisoning, as well as vaccine programs focused on filoviruses, including Ebola (SuVax™) and Marburg (MarVax™), each of which were granted Orphan designation by the FDA in April 2024. The Company is also working on a promising vaccine candidate for the prevention of COVID-19. Soligenix is utilizing a proprietary heat stabilization platform called ThermoVax® to develop its vaccine products. 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 Defense Threat Reduction Agency (DTRA), and the Biomedical Advanced Research and Development Authority (BARDA).

Specialized Biotherapeutics Pipeline


Commercial Targets: Unmet Medical Needs in Oncology and Inflammation

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

Public Health Solutions Pipeline

Funded by Government: Medical Countermeasures for Civilian & Military Use

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

Investment Highlights

- **Robust pipeline consisting of multiple fast track and/or orphan designated products, with potential for significant commercial returns of ~\$2B in global annual sales**
- **Late-stage clinical assets, one with successful Phase 3 data readout**
 - **Cutaneous T-cell lymphoma (HyBryte™ or SGX301)**
 - Positive statistically significant results achieved in first Phase 3 study; published JAMA Dermatology
 - Second confirmatory Phase 3 study of similar design accepted by EMA; FDA discussions remain ongoing
 - Significant commercial opportunity in area of unmet medical need; estimated global market potential \$250M
 - **Psoriasis (SGX302)**
 - Positive and statistically significant results achieved in Phase I/2 proof of concept study
 - Expanded Phase 2a study in mild-to-moderate psoriasis enrolling patients after demonstration of biological effect in all nine of the initial subjects
 - Significant commercial opportunity in area of unmet medical need; estimated global market potential >\$1B
 - **Aphthous Ulcers in Behçet's Disease (SGX945)**
 - FDA IND and Phase 2a protocol clearance received in Q4 2023
 - Fast-Track designation received in January 2024
 - Significant commercial opportunity in area of unmet medical need; estimated global market potential >\$200M
- **Collaborations with biotech, academia and government agencies**
- **FDA orphan drug designations recently granted to the active ingredients in the Company's MarVax™ and SuVax™ vaccine programs**
- **Non-dilutive government funding helps cover operating expenses**
 - **NIH grant awards supporting vaccine development; potential for up to 3 Priority Review Vouchers (PRVs)**
- **Experienced management team and renowned advisors with record of success**
- **\$3.75 price target from Zacks Research**

Value Proposition

Soligenix, a late-stage biopharmaceutical company, showcases a strong portfolio with several products in advanced clinical stages, targeting a potential \$2 billion in annual global sales. Notable among these is HyBryte™, a photodynamic therapy for cutaneous T-cell lymphoma (CTCL), a rare chronic cancer, which has demonstrated positive results in a Phase 3 study published in JAMA Dermatology. The company is gearing up for a follow-up confirmatory Phase 3 study, with HyBryte's market potential estimated at \$250 million. Additional promising assets include SGX302, aimed at treating psoriasis, currently in Phase 2a trials with a market potential exceeding \$1 billion, and SGX203 for pediatric Crohn's disease, pending further funding for Phase 3 trials.

Moreover, Soligenix has secured collaborations across biotech, academia, and government to advance its public health pipeline, highlighted by non-dilutive funding and NIH grants supporting vaccine development. Recently, impressive data from its filovirus vaccine program has been published, showing *complete protection in non-human primates against certain deadly viruses*, with the FDA granting orphan drug designations. Collectively, these developments make Soligenix an attractive investment, particularly with its strategic focus on unmet medical needs and robust backing through partnerships and funding.