Zacks Small-Cap Research
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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Phase 2a Psoriasis Trial Achieves Clinical Success…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SNGX is valued at $3.75 per share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based upon future clinical results.

Current Price (01/10/24)	$0.87
Valuation	**$3.75**

OUTLOOK

On January 4, 2024, Soligenix, Inc. (SNGX) announced preliminary topline results for the ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin) for the treatment of mild to moderate psoriasis. In Cohort 2, five additional patients were enrolled and treated with a more rapid escalation and higher final dose level of light than in Cohort 1. SGX302 therapy in Cohort 2 was well tolerated with no drug related adverse events. Of the four evaluable patients (one patient withdrew early for personal reasons unrelated to the study), two reached the status of "Almost Clear" with an Investigator Global Assessment (IGA) score of 1. In addition, the patients in Cohort 2 had a mean drop of approximately 50% in the Psoriasis Activity and Severity Index (PASI) score. The company will continue to test additional combinations of light intensity/duration to identify the optimal conditions for treating psoriasis patients, with a longer term goal of testing "at-home" to differentiate from other therapies as a more convenient option.

SUMMARY DATA

52-Week High	**$7.54**
52-Week Low	**$0.40**
One-Year Return (%)	**-87.81**
Beta	**1.81**
Average Daily Volume (sh)	**3,548,245**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**-0.9**
P/E using 2025 Estimate	**-0.9**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.2 A	0.2 A	0.2 A	0.4 A	0.9 A
2023	0.3 A	0.2 A	0.1 A	0.2 E	0.9 E
2024					1.0 E
2025					1.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.52 A	-$0.83 A	-$1.15 A	-$1.28 A	-$4.81 A
2023	-$0.36 A	-$0.22 A	-$0.16 A	-$0.19 E	-$0.82 E
2024					-$0.94 E
2025					-$0.95 E

WHAT'S NEW

Business Update

Additional Data Announced from Second Cohort of Patients in Phase 2a Psoriasis Trial

On January 4, 2024, Soligenix, Inc. (SNGX) announced topline data from Cohort 2 of the ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin) for the treatment of mild to moderate psoriasis. In Cohort 2, five additional patients were treated with a more rapid escalation and higher final dose level of light than in Cohort 1. These conditions are expected to more closely match how the drug will be utilized in the "real world" clinical setting.

Cohort 2 patients were treated for 18 weeks and there were no drug related adverse events reported. Four of the patients were evaluable (one patient withdrew early in the study for personal reasons unrelated to the study), with two of them achieving an Investigator Global Assessment (IGA) score of 1 ("Almost Clear"), a standard clinical measure for treatment success in psoriasis. In addition, the patients in Cohort 2 had a mean drop of approximately 50% in the Psoriasis Activity and Severity Index (PASI) score, which is an additional means to quantify clinical activity.

We spoke with management, who indicated that the company will continue to test different levels of light intensity/duration to optimize the conditions for psoriasis patients. Once the optimized conditions are established, the ultimate goal is to transition to "at home" use prior to initiating a Phase 3 trial. The ability for patients to treat themselves at home would be a clear differentiator from other psoriasis treatments on the market.

Dusquetide Granted Fast Track Designation for the Treatment of Oral Lesion of Behcet's Disease

On January 8, 2024, Soligenix announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SGX945 (dusquetide) for the treatment of oral lesions of Behcet's Disease (BD). Fast Track designation is intended to facilitate and expedite the review of new drugs and biologics that are intended to treat a serious or life-threatening condition that has an unmet medical need. In addition, Fast Track designation allows a new drug application (NDA) to be submitted on a rolling basis and NDA's for Fast Track designation programs are typically eligible for priority review.

BD is a chronic recurrent multisystemic disease that causes oral aphthous ulcers, genital ulcers, skin lesions, and other pathologies (Mendes *et al*., 2009). Interestingly, the epidemiology of BD is distributed along the ancient Silk Road from Mediterranean countries (Turkey has 370 cases per 100,000 population), to Middle Eastern and East Asian countries. In contrast, there are very few cases found in Northern Europe (0.64 cases per 100,000 population), North America (0.12-0.33 cases per 100,000 population), Australia, and Africa (Deuter *et al*., 2007). Thus, BD is an orphan disease in the U.S., however there may be as many as 500,000 people worldwide with the disease.

There are no standardized regimens for treating BD. Systemic corticosteroids, interferon-alpha (INF-α) therapy, and anti-tumor necrosis factor alpha (TNF-α) therapy are all used as first-line agents and have shown good efficacy. Apremilast (Otezla®), a phosphodiesterase 4 inhibitor, was effective in a Phase 3 clinical trial in BD patients with oral ulcers (Hatemi *et al*., 2019). It was subsequently approved by the FDA for the treatment of oral ulcers in BD patients.

Dusquetide was previously tested as a treatment for oral mucositis in which it showed biological activity against aphthous ulcers induced by chemotherapy and radiation, thus serving as a proof-of-concept for the treatment of oral ulcers in BD. We anticipate Soligenix moving dusquetide into a Phase 2 clinical trial in BD in 2024.

Study Results Showing Filovirus Vaccine Efficacy in Non-Human Primates Published in Vaccine

On January 2, 2024, Soligenix announced a publication describing results from preclinical studies showing that a novel, single-vial, bivalent vaccine provided 100% protection against both Sudan ebolavirus (SUDV) and Marburg Marburgvirus (MARV) infections (To *et al*., 2023). The vaccine is formulated with antigens from both SUDV and MARV, two members of the Filoviridae family (that includes the well-publicized Zaire ebolavirus 'Ebola virus') that have high mortality rates following infection and few treatment options outside of supportive care. In this study, macaques were immunized at weeks 0, 3, and 8 before being challenged with a lethal dose of SUDV or MARV at week 12 and then monitored for 28 days. The results showed that the vaccine candidate provided 100% protection against severe and lethal filovirus disease. Mild, subclinical infection was observed in a few macaques, however all vaccinated animals remained healthy and survived the filovirus challenge.

Using the ThermoVax technology, the company previously reported that the vaccine candidate demonstrated two-year stability at elevated temperatures (40ºC) while only needing reconstitution with sterile water immediately prior to use, thus showing its potential for use in areas that may not have the adequate infrastructure to support vaccines that require cold-chain storage.

The filovirus vaccine program is advancing through the support of National Institute of Health (NIH) grant R01-AI132323 and a Small Business Innovation Research grant (#1R44AI157593-01).

Conclusion

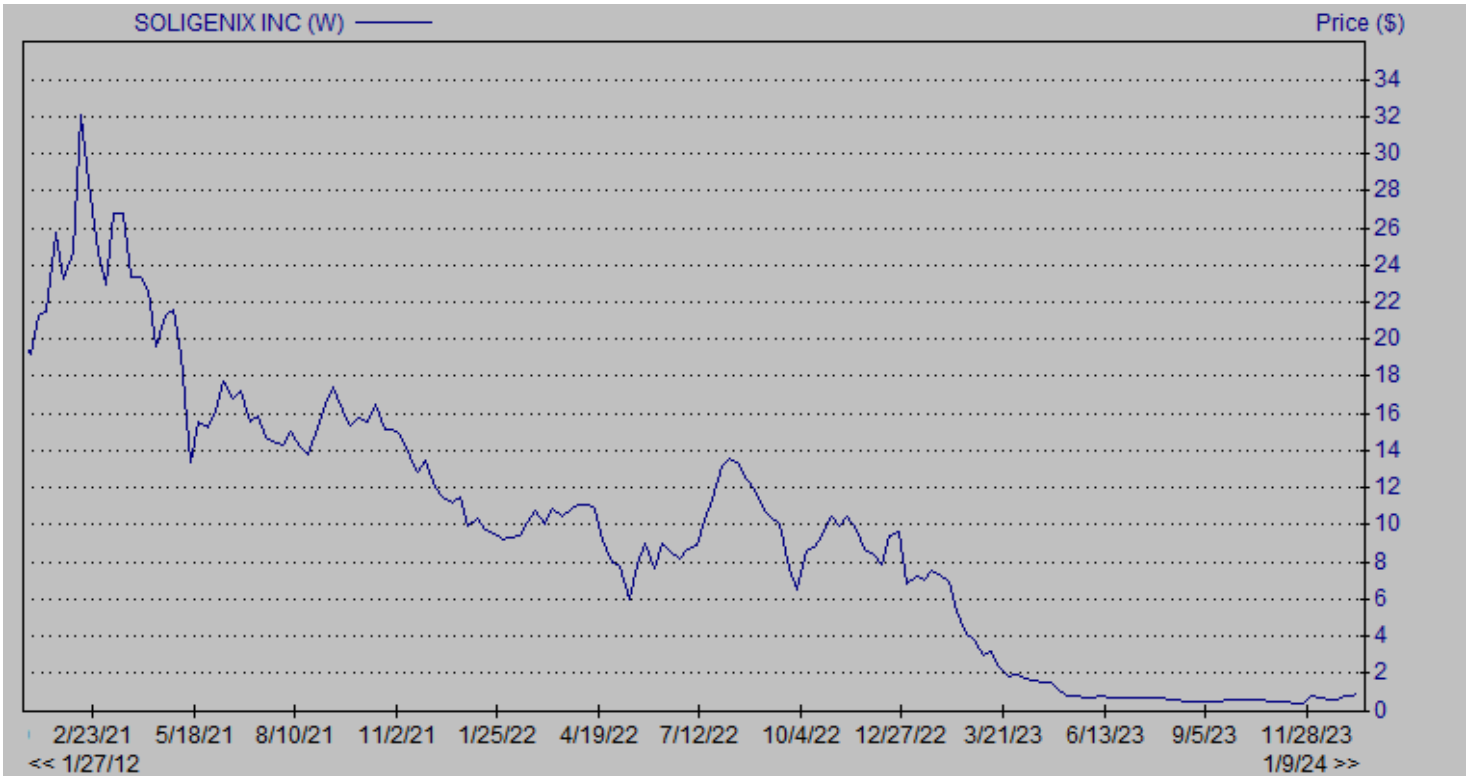
Soligenix is off to a good start in 2024 with the encouraging data from the Phase 2a study of SGX302 in psoriasis, Fast Track designation for SGX945 in Behcet's Disease, and the positive preclinical data for the filovirus vaccine candidate published in *Vaccine*. In addition, the company is continuing to work with the FDA and EMA to come to an agreement on a second Phase 3 study for HyBryte in the treatment of cutaneous T cell lymphoma (CTCL), and we expect an agreement in the first half of 2024 such that the trial can initiate in the second half of 2024. After moving our DCF model ahead one year our valuation has increased to $3.75.

PROJECTED FINANCIALS

Soligenix, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
License Revenue	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.7	$0.3	$0.2	$0.1	$0.2	$0.8	$1.0	$1.0
HyBryte	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Public Health Solutions	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.9**	**$0.3**	**$0.2**	**$0.1**	**$0.2**	**$0.8**	**$1.0**	**$1.0**
Cost of Revenue	$0.6	$0.2	$0.2	$0.1	$0.1	$0.6	$0.8	$0.8
Gross Income	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.2**	**$0.2**	**$0.2**
Gross Margin	*42.0%*	*12.1%*	*11.1%*	*15.3%*	*40.0%*	*19.4%*	*20.0%*	*20.0%*
Research & Development	$7.9	$0.9	$0.8	$0.8	$1.0	$3.5	$5.0	$6.0
General & Administrative	$6.7	$1.2	$0.9	$1.0	$1.0	$4.1	$5.0	$6.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($14.2)**	**($2.2)**	**($1.6)**	**($1.8)**	**($1.9)**	**($7.5)**	**($9.8)**	**($11.8)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.7	$0.1	$0.0	$0.1	$0.1	$0.0	$0.5	$0.5
Pre-Tax Income	**($15.0)**	**($2.2)**	**($1.6)**	**($1.7)**	**($2.0)**	**($7.5)**	**($10.3)**	**($12.3)**
Net Taxes (benefit)	$1.2	($1.2)	$0.0	$0.0	$0.0	$1.2	$0.0	$0.0
Tax Rate	*7.7%*	*52.6%*	*0.0%*	*0.0%*	*0.0%*	*15.5%*	*0.0%*	*0.0%*
Reported Net Income	**($13.8)**	**($1.0)**	**($1.6)**	**($1.7)**	**($2.0)**	**($6.3)**	**($10.3)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.81)**	**($0.36)**	**($0.22)**	**($0.16)**	**($0.19)**	**($0.82)**	**($0.94)**	**($0.95)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	2.9	7.2	10.4	10.4	7.7	11.0	13.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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