Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

May 14, 2024
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Second Confirmatory Phase 3 Trial of HyBryte™ in CTCL to Initiate Before End of 2024…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SGX302, and SGX945, SNGX is valued at $2.00 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 (05/14/24)	$0.39
Valuation	**$2.00**

OUTLOOK

On May 10, 2024, Soligenix, Inc. (SNGX) announced financial results for the first quarter of 2024 and provided a business update. The company recently completed a public offering for gross proceeds of approximately $4.75 million. This capital infusion is important as the company prepares to initiate a second Phase 3 trial of HyBryte™ (synthetic hypericin) in the treatment of cutaneous T cell lymphoma (CTCL). We anticipate the trial starting before the end of 2024, with topline results expected in the second half of 2026. We also anticipate the initiation of a Phase 2 trial of SGX945 (dusquetide) in Behcet's disease later this year, with topline results expected in the first half of 2025. Lastly, we anticipate topline results from the ongoing Phase 2 trial of SGX302 in mild-to-moderate psoriasis in the first half of 2025.

SUMMARY DATA

52-Week High	**$1.04**
52-Week Low	**$0.38**
One-Year Return (%)	**-55.92**
Beta	**1.93**
Average Daily Volume (sh)	**8,076,255**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
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	**-0.5**
P/E using 2025 Estimate	**-0.6**

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)
2023	0.3 A	0.2 A	0.1 A	0.2 A	0.8 A
2024	0.1 A	0.2 E	0.2 E	0.2 E	0.7 E
2025					1.0 E
2026					1.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.36 A	-$0.22 A	-$0.16 A	-$0.21 A	-$0.79 A
2024	-$0.18 A	-$0.13 E	-$0.14 E	-$0.14 E	-$0.58 E
2025					-$0.44 E
2026					-$0.39 E

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

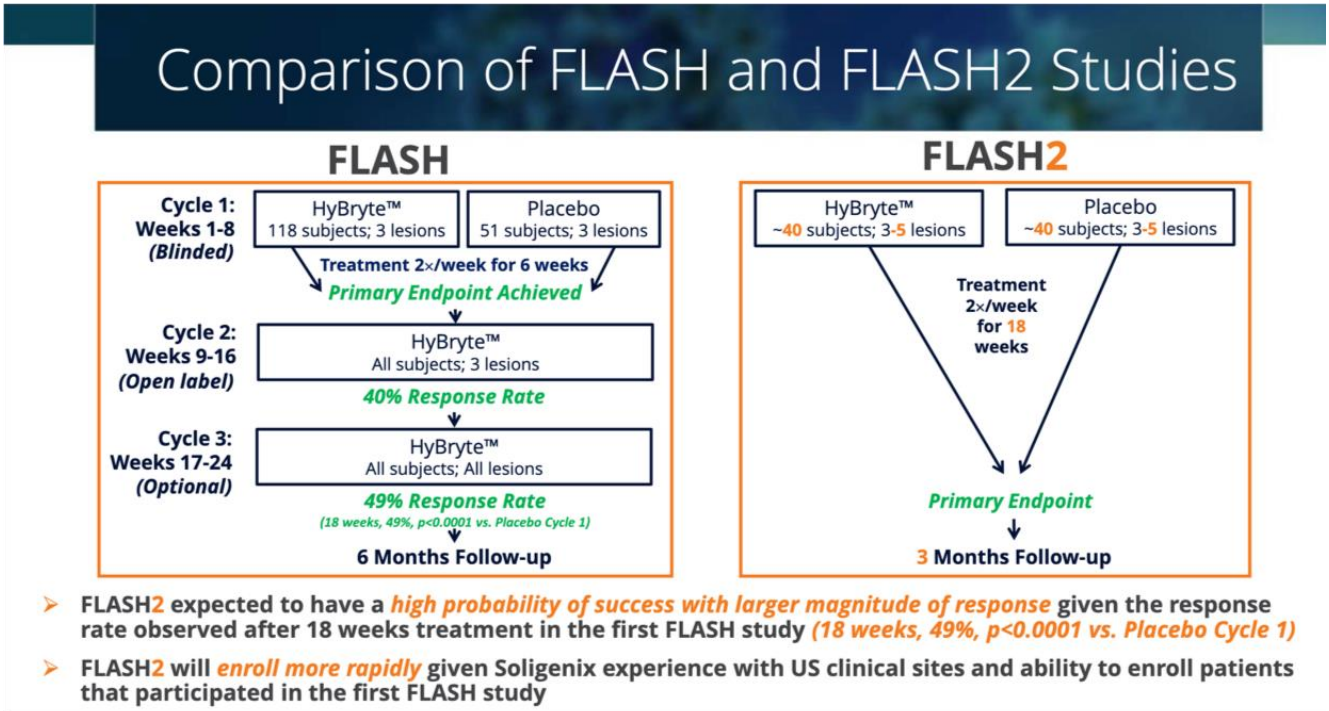
WHAT'S NEW

Business Update

Reaches Agreement with European Medicines Agency on Second Confirmatory Trial for HyBryte™

On April 3, 2024, Soligenix, Inc. (SNGX) announced it has reached agreement with the European Medicines Agency (EMA) on the key design elements for a confirmatory Phase 3 trial of HyBryte (synthetic hypericin) for the treatment of cutaneous T cell lymphoma (CTCL).

The proposed Phase 3 FLASH 2 trial will be a randomized, double blind, placebo controlled, multicenter study that will enroll approximately 80 subjects with CTCL. HyBryte will be applied topically to CTCL lesions twice weekly for 18 weeks, with each application followed 21 (± 3) hours later by the administration of visible light at a wavelength of 500 to 650 nm. The light will be administered starting at 6 J/cm^2 and will be increased upwards by 2 J/cm^2 until: 1) the patient experiences a Grade 1 erythema; 2) the patient reaches a maximum dose of 30 J/cm^2, or 3) the patient cannot tolerate the treatment time, whichever comes first. All of the subjects lesions that are readily available to the visible light source will be treated and 3 to 5 index lesions will be prospectively identified and indexed for the modified composite assessment of index lesions severity (mCAILS) evaluation prior to randomization. The primary endpoint will be assessed by the percent of patients in each treatment group (HyBryte or placebo) achieving a Partial or Complete Response of the treated lesions defined as a ≥50% reduction in the total mCAILS score for the 3-5 index lesions following 18 weeks of treatment compared to the total mCAILS score at baseline. Following treatment, subjects will be followed every 4 weeks for a total of 12 weeks (through Week 30). One interim analysis is planned after 60% of the total subjects have completed the primary endpoint evaluation. A sample size recalculation may be performed after examining the assumptions or the trial can be halted for futility, safety concerns, or overwhelming efficacy. The figure below gives a comparison between the proposed FLASH2 trial and the previously completed FLASH trial. The similarities between the two increases our confidence in a successful outcome for the FLASH2 trial.



Source: Soligenix, Inc.

We anticipate that the trial will begin enrollment prior to the end of 2024 and topline results are expected in the second half of 2026. The company is continuing discussions with the U.S. Food and Drug Administration

(FDA) on an appropriate study design as the agency has expressed a preference for a longer duration comparative study over a placebo-controlled trial.

Orphan Drug Designation for Marburg Marburgvirus Vaccine

On April 15, 2024, Soligenix announced that the U.S. FDA has granted orphan drug designation (ODD) to the active ingredient in MarVax™, the subunit protein vaccine of recombinantly expressed *Marburg marburgvirus* (MARV) glycoprotein, for "the prevention and post-exposure prophylaxis against MARV infection".

ODD is designed to assist companies that are developing therapies for rare diseases and disorders, defined as those that affect 200,000 people or fewer in the U.S. Drugs granted ODD receive a seven year term of market exclusivity upon final FDA approval. In addition, financial and regulatory benefits are available including government grants to conduct clinical trials, waiver of FDA user fees, and certain tax credits.

MarVax addresses the potentially lethal Marburg Virus Disease caused by MARV. While vaccines exist for *Zaire ebolavirus*, they are ineffective against MARV. MarVax is based on the company's novel vaccine platform that consists of a robust protein manufacturing process, a nano-emulsion adjuvant that induces a strong immune response, and thermostabilization of the adjuvant and antigen in a single vial that is stable at elevated temperatures for extended timeframes.

Patent Protection Extended for Filovirus Vaccine Platform

On April 25, 2024, Soligenix announced it received notice of intent to grant additional patents based on its patent application titled "Compositions and Methods of Manufacturing Trivalent Filovirus Vaccines" in the United Kingdom and South Africa, with other jurisdictions pending. Multiple patents have previously been issued in the U.S. within the same patent family. The described vaccine platform was previously used to successfully produce mono-, bi-, and tri-valent candidates for *Zaire ebolavirus*, *Sudan ebolavirus*, and *Marburg marburgvirus*.

Financial Update

On May 10, 2024, Soligenix announced financial results for the first quarter of 2024. The company reported revenues of $0.1 million for the first quarter of 2024, compared to $0.3 million for the first quarter of 2023. The revenues are derived from government contracts and grants to support the development of SGX943 for treatment of emerging and/or antibiotic resistant infectious diseases, development of CiVax™, and evaluation of HyBryte for expanded treatment in patients with early-stage CTCL. R&D expenses for the first quarter of 2024 were $1.1 million, compared to $0.9 million for the first quarter of 2023. The increase was primarily due to an increase in preliminary costs associated with the anticipated initiation of the Phase 2 study in Behcet's Disease and the second confirmatory Phase 3 CTCL trial. G&A expenses for the first quarter of 2024 were $1.0 million, compared to $1.2 million for the first quarter of 2023. The decrease was primarily due to a decrease in legal and professional fees.

Soligenix exited the first quarter of 2024 with approximately $4.3 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised gross proceeds of $4.75 million through the sale of 11.875 million shares at $0.40 per share along with 11.875 million warrants with an exercise price of $0.40 per share and a five-year expiration date. As of May 3, 2024, Soligenix had approximately 15.8 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 45.7 million.

Conclusion

We look forward to the initiation of the second confirmatory Phase 3 clinical trial of HyBryte and we're confident that the FDA will come to an agreement with the company soon on its preferences for the trial. After taking into account the recent financing our valuation is now at $2.00 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$0.8	$0.1	$0.2	$0.2	$0.2	$0.7	$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	**$0.8**	**$0.1**	**$0.2**	**$0.2**	**$0.2**	**$0.7**	**$1.0**	**$1.0**
Cost of Revenue	$0.7	$0.1	$0.2	$0.2	$0.2	$0.7	$0.8	$0.8
Gross Income	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.2**	**$0.2**
Gross Margin	*11.6%*	*0.0%*	*10.0%*	*10.0%*	*10.0%*	*8.4%*	*20.0%*	*20.0%*
Research & Development	$3.3	$1.1	$0.9	$1.0	$1.0	$4.0	$4.0	$4.2
General & Administrative	$4.5	$1.0	$1.2	$1.2	$1.2	$4.6	$5.0	$5.3
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.7)	($2.1)	($2.1)	($2.2)	($2.2)	($8.6)	($8.8)	($9.3)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	**($7.9)**	**($1.9)**	**($2.1)**	**($2.2)**	**($2.2)**	**($8.4)**	**($8.8)**	**($9.3)**
Net Taxes (benefit)	$1.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*22.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($6.1)**	**($1.9)**	**($2.1)**	**($2.2)**	**($2.2)**	**($8.4)**	**($8.8)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.79)**	**($0.18)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.58)**	**($0.44)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	7.8	10.5	15.8	15.8	16.0	14.5	20.0	24.0

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

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.