Zacks Small-Cap Research
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David Bautz, PhD
312-265-9471
dbautz@zacks.com

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

Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Filovirus Vaccine Candidates Demonstrate Two-Year Stability at Elevated Temperature…

Based on our probability adjusted DCF model that takes into account potential future revenues from HyBryte™, SNGX is valued at $3.50 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 (11/20/23)	$0.40
Valuation	**$3.50**

OUTLOOK

On November 13, 2023, Soligenix, Inc. announced financial results for the third quarter of 2023 and provided a business update. The company recently announced that its filovirus vaccine candidates achieved two-year stability when stored at elevated temperature (40ºC) and needing only reconstitution with sterile water immediately prior to use. This is an excellent proof-of-concept for the company's heat stable vaccine platform and its robust thermostabilization capabilities.

Soligenix continues to enroll patients in the ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin sodium) for the treatment of mild-to-moderate psoriasis following demonstration of a clear biological signal in the first five patients treated in the study. In addition, the company is continuing its discussion with the FDA regarding the design of a second Phase 3 trial for HyBryte in CTCL.

SUMMARY DATA

52-Week High	**$10.06**
52-Week Low	**$0.40**
One-Year Return (%)	**-95.90**
Beta	**1.46**
Average Daily Volume (sh)	**60,879**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$4**
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 2018 Estimate	**-0.2**
P/E using 2019 Estimate	**-0.3**

Risk Level	**Above Avg.**
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

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WHAT'S NEW

Business Update

Filovirus Vaccine Candidates Demonstrate Two-Year Stability at Elevated Temperatures

In September 2023, Soligenix, Inc. (SNGX) announced that its thermostabilized bivalent and trivalent filovirus vaccine candidates demonstrated two-year stability at elevated temperatures (40ºC) while only needing reconstitution with sterile water immediately prior to use. This data shows the broad applicability of the company's ThermoVax heat stabilization technology and its potential for use in areas that may not have the adequate infrastructure to support vaccines that require cold-chain storage.

The company had previously reported 100% protection of non-human primates against both Sudan ebolavirus (SUDV) and Marburg Marburgvirus (MARV) using a bivalent thermostabilized filovirus vaccine. Both SUDV and MARV are highly lethal viruses that can cause outbreaks in areas of the world where access to reliable power sources and distribution channels are sometimes limited. Thus, a heat stable vaccine that can offer protection against both viruses would be an important public health asset that could be utilized to help limit outbreaks.

Filoviruses are one of the virus families recognized as being capable of causing a pandemic, thus effective vaccines against members of that family are clearly warranted. There are currently approved vaccines for Ebola virus (however they require cold-chain storage) and limited treatment options, however no approved vaccines or treatments are available for MARV or SUDV. A number of outbreaks of Ebola virus and MARV have occurred since the mid-20th century, including one in 2014 that killed >11,000 people (CDC).

Expanding SGX302 Phase 2a Study in Mild-to-Moderate Psoriasis

In July 2023, Soligenix, announced that the company will be expanding the ongoing Phase 2a clinical trial of SGX302 (synthetic hypericin) in patients with mild-to-moderate psoriasis. A clear biological signal was seen following evaluation of the first five subjects enrolled in the trial as evidenced by an improvement in the PASI (psoriasis area and severity index) score. At least an additional five patients will now be enrolled into the trial, which will allow Soligenix to evaluate SGX302 in the context of accelerated light treatment and additional adjunct treatment. We anticipate topline results from this portion of the trial before the end of 2023.

The Phase 2a trial is a randomized, double blind, placebo controlled study this is enrolling patients with mild-to-moderate, stable psoriasis covering 2% to 30% of their body. Placebo or SGX302 is being administered twice weekly for up to 18 weeks, with each treatment consisting of application followed approximately 24 hours later with visible light activation. The efficacy endpoints include lesion clearance along with patient quality of life indices.

Update on FDA Interactions for HyBryte

In April 2023, Soligenix conducted a Type A meeting with the FDA regarding the design of a second Phase 3 clinical trial for HyBryte in the treatment of cutaneous T cell lymphoma (CTCL). The FDA will require a second, confirmatory study with a longer comparative treatment duration than was conducted in the FLASH study to support an NDA filing for HyBryte in CTCL. We spoke with Soligenix management and learned that while they do not have a final FDA agreement as yet, they remain in active discussions with the FDA and will be communicating the outcome of these interactions as soon as possible once they have definitive clarity. Dr. Schaber noted that, while he had hoped the process would have moved a bit quicker, it's important to maintain positive and productive dialogue when working to gain potential agreement on a feasible and highly executable clinical trial design. The company anticipates having that clarity before the end of the year and will update investors as soon as possible.

Financial Update

On November 13, 2023, Soligenix announced financial results for the third quarter of 2023. The company reported revenues of $0.13 million for the third quarter of 2023, compared to $0.17 million for the third quarter of 2022. The decrease was primarily due to the conclusion of the grant associated with the development of SGX943. R&D expenses for the third quarter of 2023 were $0.8 million, compared to $1.8 million for the third quarter of 2022. The decrease was primarily due to a decrease in manufacturing costs associated with the HyBryte NDA filing. G&A expenses for the third quarter of 2023 were $1.0 million, compared to $1.3 million for the third quarter of 2022. The decrease was primarily due to a decrease in legal and consulting services associated with the arbitration against Emergent BioSolutions, Inc.

Soligenix exited the third quarter of 2023 with approximately $10.3 million in cash and cash equivalents. As of November 6, 2023, Soligenix had approximately 10.4 million shares outstanding and, when factoring in stock options, warrants, and the potential convertible debt, a fully diluted share count of approximately 19.3 million. The company is continuing to evaluate all strategic options, including partnership and M&A opportunities.

Conclusion

Soligenix continues to generate positive data for its vaccine platform, and the recently announced stability data should be viewed by investors as applicable to the entire platform and not specifically just for the filovirus vaccine candidates. We look forward to updates from the company as it works with the FDA on designing an additional Phase 3 clinical trial for HyBryte in the treatment of CTCL. In addition, we anticipate the company providing an update on the Phase 2a trial of SGX302 in psoriasis. With no changes to our model, our vauation remains at $3.50 per share.

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*

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