Zacks Small-Cap Research

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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Positive Preclinical Data for Filovirus Vaccine Candidates…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301 and CiVax, SNGX is valued at $6.00 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 (08/19/21)	$0.96
Valuation	**$6.00**

OUTLOOK

On August 13, 2021, Soligenix, Inc. (SNGX) announced financial results for the second quarter of 2021 and provided a business update. Results from the company's Phase 3 FLASH trial were recently selected for presentation at the United States Cutaneous Lymphoma Consortium (USCLC) Annual Meeting and HyBryte™ (SGX301) received a Pediatric Investigation Plan (PIP) waiver from the European Medicines Agency (EMA), a key component of the regulatory process in Europe. We continue to anticipate an NDA filing for HyBryte in the first half of 2022. On August 18, 2021, the company announced positive preclinical results for multiple heat stable filovirus vaccine candidates that utilize purified antigens and CoVaccine HT™ adjuvant were published in *Frontiers in Immunology*. The U.S. government may pursue a broad program to develop prototype vaccines for pandemic potential pathogens, for which Soligenix's vaccine platform could be utilized.

SUMMARY DATA

52-Week High	**$2.75**
52-Week Low	**$0.87**
One-Year Return (%)	**-55.40**
Beta	**1.30**
Average Daily Volume (sh)	**804,751**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$38**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-30.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.5**
P/E using 2019 Estimate	**-1.8**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.9 A	0.5 A	0.6 A	0.3 A	2.4 A
2021	0.1 A	0.2 A	0.8 E	0.8 E	2.5 E
2022					4.5 E
2023					14.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.32 A	-$0.10 E	-$0.06 A	-$0.18 A	-$0.64 A
2021	-$0.06 A	-$0.05 A	-$0.16 E	-$0.18 E	-$0.48 E
2022					-$0.66 E
2023					-$0.47 E

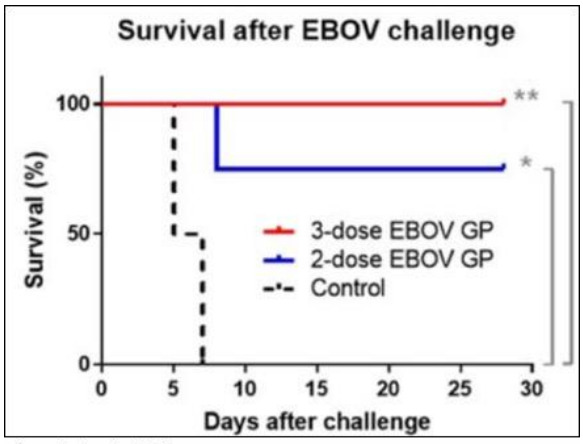
WHAT'S NEW

Business Update

Positive Preclinical Data for Filovirus Vaccine Candidates

On August 18, 2021, Soligenix, Inc. (SNGX) announced positive preclinical data for three filovirus vaccine candidates in non-human primates (NHPs) was published in the peer reviewed journal *Frontiers in Immunology*. The article, titled "Recombinant Protein Filovirus Vaccines Protect Cynomolgus Macaques from Ebola, Sudan, and Marburg Viruses", describe the efficacy of vaccine candidates targeting *Zaire ebolavirus* (EBOV), *Sudan ebolavirus* (SUDV), and *Marburg Marburgvirus* (MARV) (Lehrer *et al*., 2021).

The vaccine candidates contain highly purified protein antigens combined with CoVaccine HT™ adjuvant with both monovalent and bivalent formulations. Animals were vaccinated intramuscularly with purified recombinant glycoproteins (GPs) from EBOV, SUDV, and/or MARV and then challenged with virus 10 weeks after the first immunization. The following image shows that following three doses of EBOV GP, 100% of animals are protected from infection by EBOV, with 3/4 animals receiving two doses surviving (with a concomitant decline in IgG antibody titer) and all control animals perishing from Ebola virus disease by day 7 after viral challenge.



Source: Lehrer *et al.*, 2021

Similar results were seen following immunization with SUDV GP or MARV GP and subsequent infection with SUDV or MARV, respectively. Combination formulations containing both EBOV GP and SUDV GP or MARV GP and EBOV GP were also 100% successful in preventing death following infection, thus showing that vaccines with multiple antigens do not lose efficacy.

The technology underlying the filovirus vaccines is the same that is being utilized to develop CiVax™, the company's COVID-19 vaccine candidate. CiVax consists of a recombinant spike protein from the SARS-CoV-2 virus (which causes COVID-19) that is expressed in an insect cell expression system to ensure stable glycosylation patterns. It has previously been shown to induce rapid onset, broad-spectrum, neutralizing antibody and cell-mediated immunity. CiVax uses Soligenix's thermostabilization platform, ThermoVax®, that allows for individually lyophilized samples to be prepared that can be reconstituted with sterile water immediately prior to administration. Lyophilized samples of other vaccines using the ThermoVax technology have demonstrated stability at 40ºC for at least 12 weeks.

Another important aspect of the company's vaccine technology is its potential use to develop prototype vaccines for 20 different virus families that could potentially cause a pandemic, an idea originally put forth in 2017 by Dr. Barney Graham, the deputy director of the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases, but given renewed focus by Dr. Anthony Fauci in light of the ongoing coronavirus epidemic. Dr. Fauci is now pushing for Congress to fund the project, which if approved could begin in 2022. We believe the positive preclinical data collected so far for Soligenix's vaccine candidates show it to be an ideal platform for developing vaccines to the current and any future pandemic outbreaks.

NDA Submission for SGX301 in 1H22

Soligenix is developing SGX301 (HyBryte™) for the treatment of cutaneous T cell lymphoma (CTCL). The company has successfully completed the Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, which was a randomized, double blind, placebo controlled study that enrolled 169 patients with either Stage IA, IB, or IIA mycosis fungoides (the most common type of CTCL) (NCT02448381). Results from the trial showed that administration of SGX301 results in a rapid treatment effect, with efficacy seen as soon as six weeks following initiation of treatment (Cycle 1; P=0.04), a continued improvement in patient response following 12 weeks of treatment (Cycle 2; P<0.0001 compared to Cycle 1), and approximately 50% of patients receiving treatment for 18 weeks reported a 50% or greater reduction in response rates (Cycle 3; P<0.0001 compared to Cycle 1). The company presented key details from the FLASH study at the United States Cutaneous Lymphoma Consortium (USCLC) Annual Meeting in June 2021, with the audience consisting of key disease state experts and potential future prescribers of the drug, if approved.

The company will be filing an NDA with the U.S. FDA in the first half of 2022. In addition, Soligenix recently announced it received a Pediatric Investigation Plan (PIP) waiver from the European Medicines Agency (EMA) for HyBryte. Part of the regulatory process with the EMA involves submitting a PIP that describes how the drug will be investigated in a pediatric population. For drugs in which development in children is not feasible or appropriate (such as the case with HyBryte), a PIP waiver can be granted. Now that the company has a PIP waiver, it can focus on advancing a marketing authorization application (MAA) with the EMA in a more cost-efficient manner.

Financial Update

On August 13, 2021, Soligenix announced financial results for the second quarter of 2021. The company reported revenues of $0.2 million for the second quarter of 2021, compared to $0.5 million for the second quarter of 2020. The revenues are derived from government grants to support the development of SGX943, ThermoVax®, and CiVax®. R&D expenses for the second quarter of 2021 were $2.1 million, compared to $2.2 million for the second quarter of 2020. The decrease was primarily due to the completion of the CTCL and oral mucositis trials. G&A expenses for the second quarter of 2021 and 2020 were both $0.9 million and $0.8 million, respectively.

Soligenix exited the second quarter of 2021 with approximately $29.0 million in cash and cash equivalents. As of August 11, 2021, Soligenix had approximately 40.1 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 50.3 million.

Conclusion

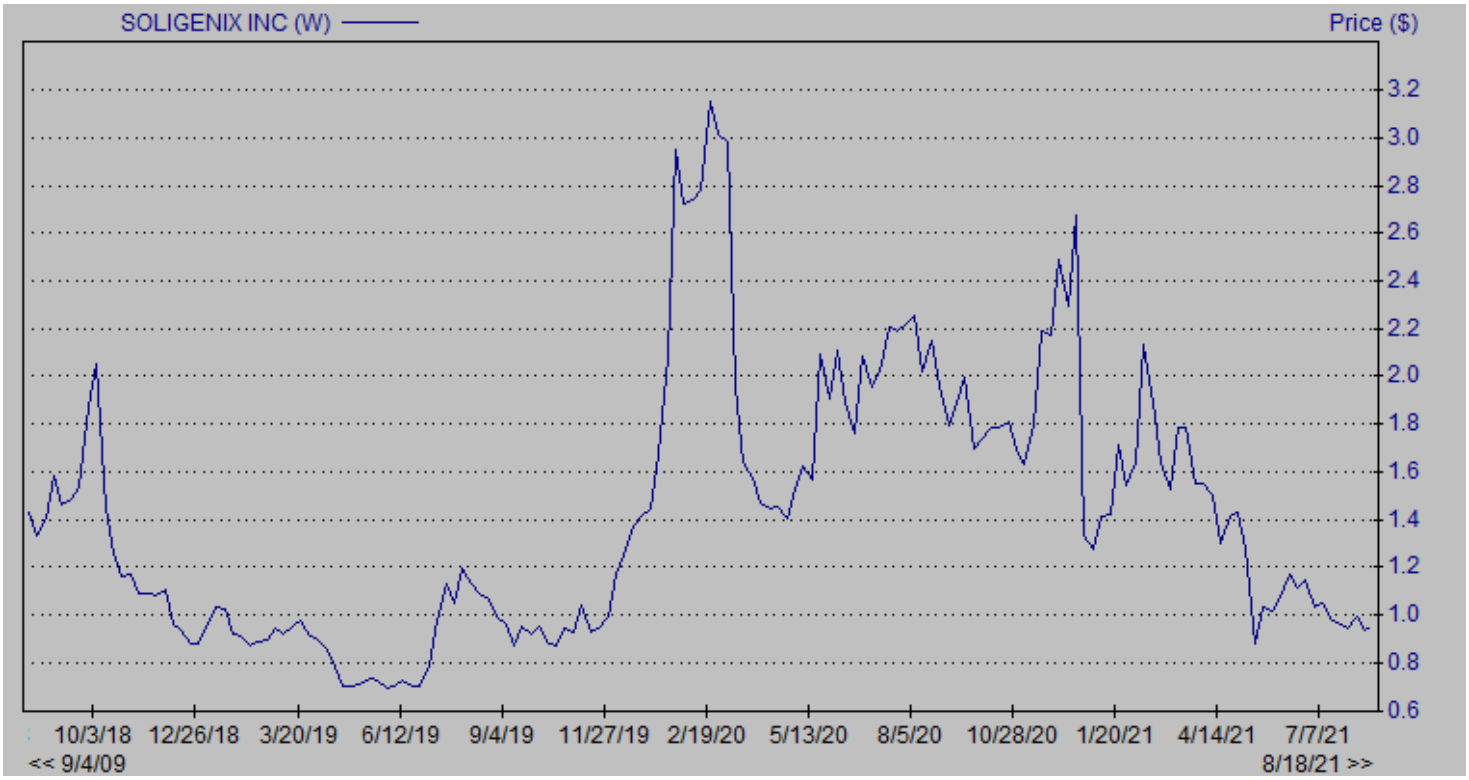
The company's vaccine platform continues to perform well with the positive preclinical data on the filovirus vaccine candidates. A large government program dedicated to expediting the development of prototype vaccines for potential pandemic threats could be a great opportunity for the company, and we will keep a close eye on any news on that program as the year goes on. Soligenix has a strong balance sheet that will carry it through important upcoming milestones, including filing the NDA for HyBryte in the first half of 2022. With no changes to our model our valuation remains at $6.00 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$2.4	$0.1	$0.2	$0.8	$0.8	$2.0	$4.5	$4.5
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$10.0
Public Health Solutions	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$2.4**	**$0.1**	**$0.2**	**$0.8**	**$0.8**	**$2.0**	**$4.5**	**$14.5**
Cost of Revenue	$1.8	$0.1	$0.2	$0.6	$0.6	$1.5	$5.4	$6.5
Gross Income	**$0.5**	**$0.0**	**$0.0**	**$0.2**	**$0.2**	**$0.4**	**$0.9**	**$8.0**
Gross Margin	*22.8%*	*17.1%*	*4.9%*	*25.0%*	*25.0%*	*22.2%*	*-20.0%*	*55.2%*
Research & Development	$10.1	$1.4	$2.1	$4.0	$4.5	$12.0	$16.0	$17.0
General & Administrative	$4.0	$0.9	$0.9	$2.8	$3.5	$8.1	$15.0	$16.0
Other Expenses	$5.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($18.6)	($2.2)	($3.0)	($6.6)	($7.8)	($19.6)	($31.9)	($25.0)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.1	$0.1	$0.2	$0.2	$0.2	$0.3	$0.9	$0.8
Pre-Tax Income	**($18.5)**	**($2.4)**	**($2.8)**	**($6.8)**	**($8.0)**	**($20.0)**	**($32.8)**	**($25.8)**
Net Taxes (benefit)	$0.8	$0.0	($0.9)	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*4.5%*	*0.0%*	*31.3%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($17.7)**	**($2.4)**	**($1.9)**	**($6.8)**	**($8.0)**	**($20.0)**	**($32.8)**	**($25.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.64)**	**($0.06)**	**($0.05)**	**($0.16)**	**($0.18)**	**($0.48)**	**($0.66)**	**($0.47)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	27.5	36.8	40.1	43.0	45.0	41.2	50.0	55.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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