

Zacks Small-Cap Research

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Soligenix, Inc.

(SNGX-NASDAQ)

SNGX: CiVax™ Shows Protective Effects Against SARS-CoV-2 Variant in Non-Human Primates...

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 (09/29/21) \$1.10
Valuation \$6.00

OUTLOOK

On September 28, 2021, Soligenix, Inc. (SNGX) announced the publication of preclinical immunogenicity studies for CiVax™, the company's heat stable COVID-19 vaccine candidate. The studies were undertaken in non-human primates (NHPs), which were vaccinated twice, three weeks apart, before being challenged with the SARS-CoV-2 Gamma variant. The CiVax™ S protein is based on the original SARS-CoV-2 virus, however vaccinated animals had lower peak viral load and more rapid resolution of infectious virus even when challenged with the Gamma variant. While the current batch of mRNA vaccines are highly effective at preventing severe disease, data is lacking on their long-term efficacy and protection against variants of concern. In addition, cold chain requirements for those vaccines preclude their use in many third-world countries, thus presenting a potential opportunity for a heat-stable vaccine such as CiVax™.

SUMMARY DATA

52-Week High \$2.75
52-Week Low \$0.87
One-Year Return (%) -38.20
Beta 1.31
Average Daily Volume (sh) 4,375,117

Shares Outstanding (mil) 40
Market Capitalization (\$mil) \$44
Short Interest Ratio (days) N/A
Institutional Ownership (%) 10
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 -2.9
P/E using 2019 Estimate -2.2

Risk Level Above Avg.
Type of Stock Small-Blend
Industry Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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

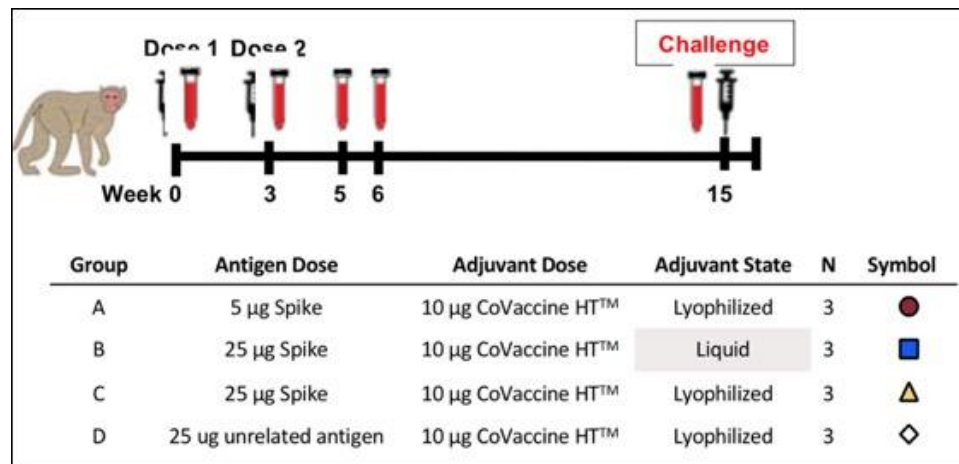
	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2020	-\$0.32 A	-\$0.10 E	-\$0.06 A	-\$0.18 A	-\$0.64 A
2021	-\$0.06 A	-\$0.05 A	-\$0.16 E	-\$0.18 E	-\$0.48 E
2022					-\$0.66 E
2023					-\$0.47 E

WHAT'S NEW

Business Update

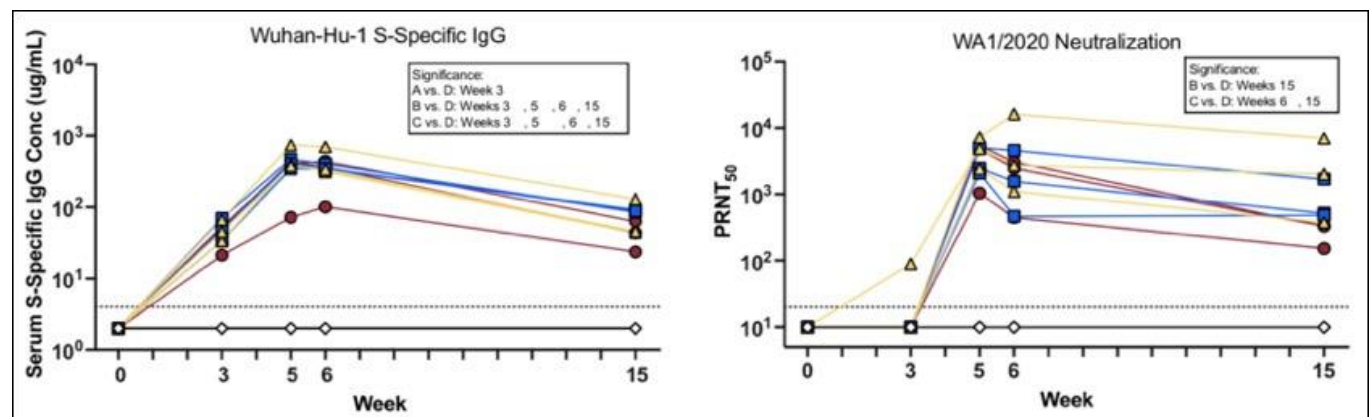
CiVax™ Shows Protective Effects Against SARS-CoV-2 Variant in NHP

On September 28, 2021, Soligenix, Inc. (SNGX) [announced](#) the publication of pre-clinical immunogenicity studies for CiVax™, the company's heat-stable COVID-19 vaccine candidate ([To et al., 2021](#)). CiVax™ is composed of a recombinant pre-fusion spike subunit (based on the reference SARS-CoV-2 strain, Wuhan-Hu-1) adjuvanted with liquid or lyophilized CoVaccine HT™. Twelve cynomolgus monkeys were immunized twice with 5 (Group A, n=3) or 25 (Group B and C) µg of spike protein antigen formulated with either lyophilized (Group A and C) or liquid (Group B) CoVaccine HT™ adjuvant. Group D served as a control and received one dose of a co-lyophilized CoVaccine HT™-adjuvanted unrelated viral glycoprotein antigen. An overview of the different dosing groups and administration schedule is shown below.



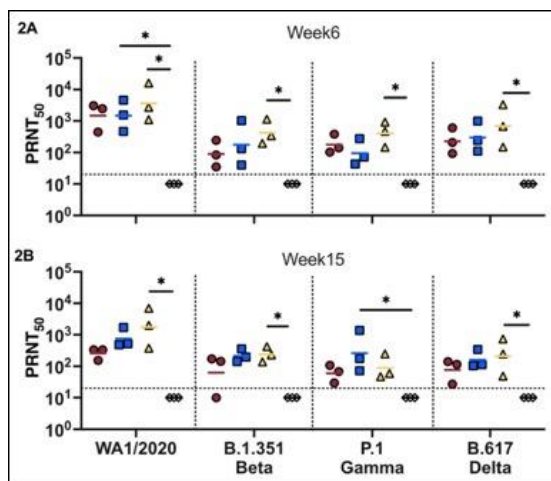
Source: To et al., 2021

The two doses of spike protein were administered three weeks apart and all macaques were then challenged with 1×10^6 TCID₅₀ of the P.1 isolate (Gamma variant) of SARS-CoV-2 12 weeks post-boost (study week 15). The following figures show that all macaques immunized with S protein seroconverted following the boost at week 3 (one macaque from the C group seroconverted after the first dose), with peak serum IgG concentrations detected at week 5. By week 15, IgG concentrations had dropped 3.0 to 9.9-fold relative to the peak titer. Total S protein-specific IgG is shown on the lower left and neutralizing antibody titers are shown on the lower right.



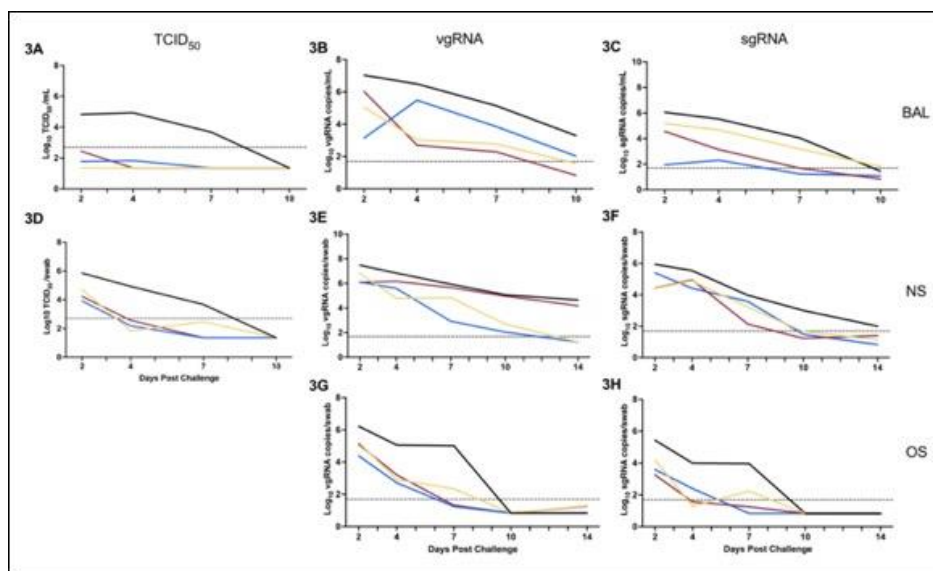
Source: To et al., 2021

To test whether the Wuhan-Hu-1 S protein could generate durable cross-variant neutralizing antibodies, a PRNT assay was performed using sera collected at week 6 and week 15 against the WA1/2020, B.1.351 (Beta), P.1 (Gamma), and B.1.617 (Delta) SARS-CoV-2 variants, as shown in the following figures. At week 6, potent neutralization of all variants was detected, although 10.7-, 10.7-, and 5.7-fold lower against the B.1.351, P.1, and B.1.617 variants compared to the WA1/2020 strain, respectively. By week 15, the gap between neutralization titers against the WA1/2020 and other strains narrowed, mostly due to waning of titers against WA1/2020.



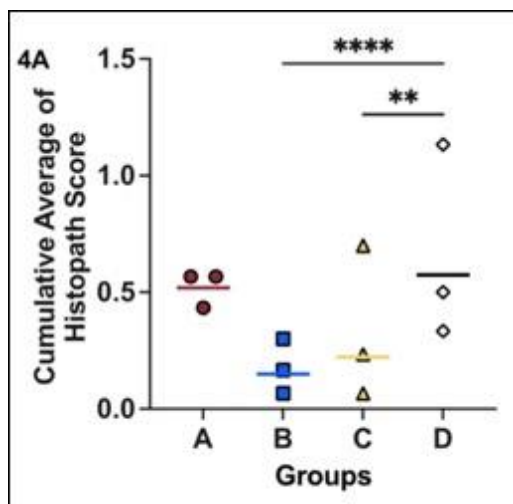
Source: To *et al.*, 2021

To determine if the spike protein is capable of reducing viral load, all NHPs were challenged with a total of 1×10^6 TCID₅₀ of the P.1 SARS-CoV-2 isolate using simultaneous intranasal and intratracheal inoculations. Consistent with previous studies of SARS-CoV-2 in NHPs, none of the challenged macaques showed visible clinical signs of respiratory distress throughout the study. Bronchioalveolar lavages (BAL) from the lower respiratory tract and nasal (NS) and oral swabs (OS) from the upper respiratory tract were collected at days 2, 4, 7, 10, and 14 after challenge. High levels of virus were recovered from control animals two days post-challenge from the NS and BAL (black lines in below figure 3A and 3D). Virus was detectable from both sites up through day 7 post challenge and then became undetectable on day 10. All S-immunized NHPs had viral titers 1-2 Log₁₀ lower than control animals from both the upper and lower respiratory tract throughout the study. Infectious virus from the NS was recoverable from immunized animals throughout the study period, however it was also 1-2 Log₁₀ below those of control animals. In the following figures, vgRNA = viral genomic RNA and sgRNA = subgenomic N RNA, indicating the presence of viral RNA and viral replication, respectively.



Source: To *et al.*, 2021

While NHPs show no outward visible signs of illness upon infection with SARS-CoV-2, infected animals are still susceptible to acute lung injury upon microscopic evaluation of lung tissue. Histopathological evaluation of lung lobe and bronchi following staining with hematoxylin and eosin showed significant differences in the cumulative average score (based on the presence/severity of edema, intraalveolar and interstitial inflammation, perivascular lymphocytic cuffing, and increased bronchiolar-associated lymphoid tissue) for each vaccine formulation compared to controls. The cumulative average histopathology scores for all animals are shown in the following figure. Group D macaques showed mild to moderate respiratory disease, while all animals except one from Groups B and C were completely protected from lung pathology. All Group A macaques appeared to develop mild disease despite having lower viral loads.



Source: To *et al.*, 2021

Conclusion

The data generated for the prefusion S protein formulated with CoVaccine HT™ is very encouraging and shows that it generates a high level of neutralizing antibodies against the SARS-CoV-2 virus while protecting NHPs from any type of lung pathology at the higher dose. While a number of different COVID-19 vaccines are currently available, their requirements for cold chain shipping have limited their availability in a number of areas around the world. Previous work with CoVaccine HT adjuvant shows it is thermostable in combination with multiple different types of antigens, thus CiVax™ would not require cold chain distribution or storage. We look forward to additional updates from the company as it plans to approach various funding agencies with these latest results to discuss funding options to advance the CiVax™ program. Our valuation remains at \$6.00 per share.

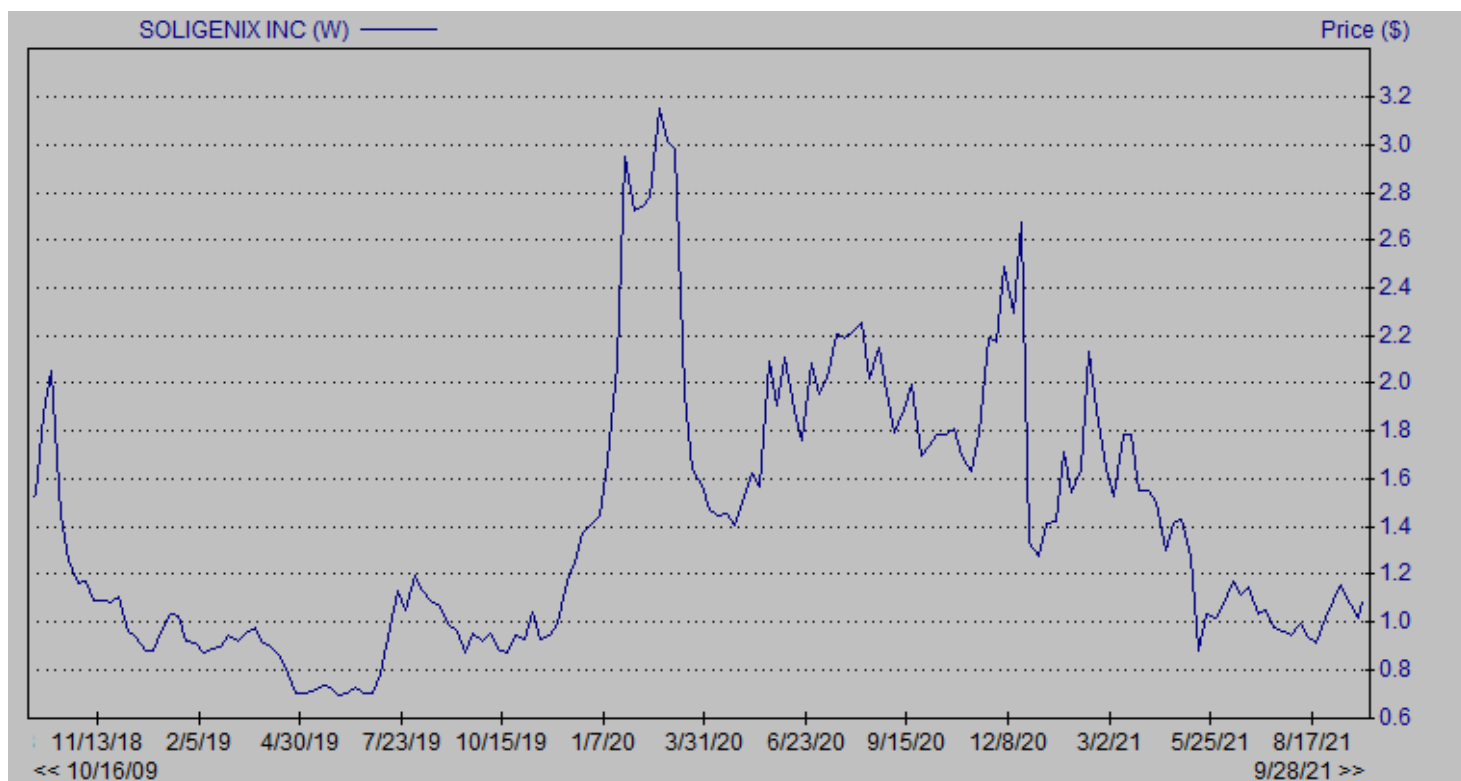
PROJECTED FINANCIALS

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
<i>Gross Margin</i>	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)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
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
<i>Tax Rate</i>	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)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.64)	(\$0.06)	(\$0.05)	(\$0.16)	(\$0.18)	(\$0.48)	(\$0.66)	(\$0.47)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
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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