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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Multiple Upcoming Catalysts…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301 and SGX942, SNGX is valued at $12.00 per share. This model is highly dependent upon continued clinical success of SGX301 and SGX942 and will be adjusted accordingly based upon future clinical results.

Current Price (08/17/20)	$2.03
Valuation	**$12.00**

OUTLOOK

On August 14, 2020, Soligenix, Inc. (SNGX) announced financial results for the second quarter of 2020 and provided a business update. Earlier in 2020, the company announced positive results from the Phase 3 trial of SGX301 in cutaneous T cell lymphoma (CTCL) and we anticipate results from Cycle 3 in the fourth quarter of 2020. The company is also conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial of SGX942 (dusquetide) for the treatment of severe oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. We anticipate topline results in the fourth quarter of 2020. Soligenix also recently provided an update on CiVax™ (heat stable COVID-19 vaccine candidate) that demonstrated broad-spectrum antibody and cell-mediated immunity in an animal model. We anticipate an update on the CiVax™ program during the second half of 2020.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.87**
One-Year Return (%)	**84.54**
Beta	**1.35**
Average Daily Volume (sh)	**2,428,124**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$59**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-16.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-3.0**
P/E using 2019 Estimate	**-5.2**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	1.1 A	1.5 A	1.3 A	0.7 A	4.6 A
2020	0.9 A	0.5 A	1.1 E	1.1 E	3.6 E
2021					4.5 E
2022					25.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.09 A	-$0.12 E	-$0.14 A	-$0.16 A	-$0.48 A
2020	-$0.32 A	-$0.10 A	-$0.10 E	-$0.11 E	-$0.60 E
2021					-$0.58 E
2022					-$0.34 E

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Business Update

Phase 3 DOM-INNATE Results in 4Q20

Soligenix, Inc. (SNGX) is currently conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) trial of SGX942 in the treatment of oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. In June 2020, the company announced that the trial was fully enrolled with 268 patients. For an overview of the DOM-INNATE trial, please see our previous Q&A with Dr. Richard Straube, Soligenix's Chief Medical Officer.

The company had previously received a positive recommendation from the Independent Data Monitoring Committee (DMC) in Aug. 2019 to continue enrollment in the trial and that approximately 70 additional subjects be randomized into the trial to maintain the 90% statistical power for the primary outcome. We anticipate topline results from the trial in the fourth quarter of 2020.

Results from Cycle 3 of Phase 3 FLASH Trial in 4Q20

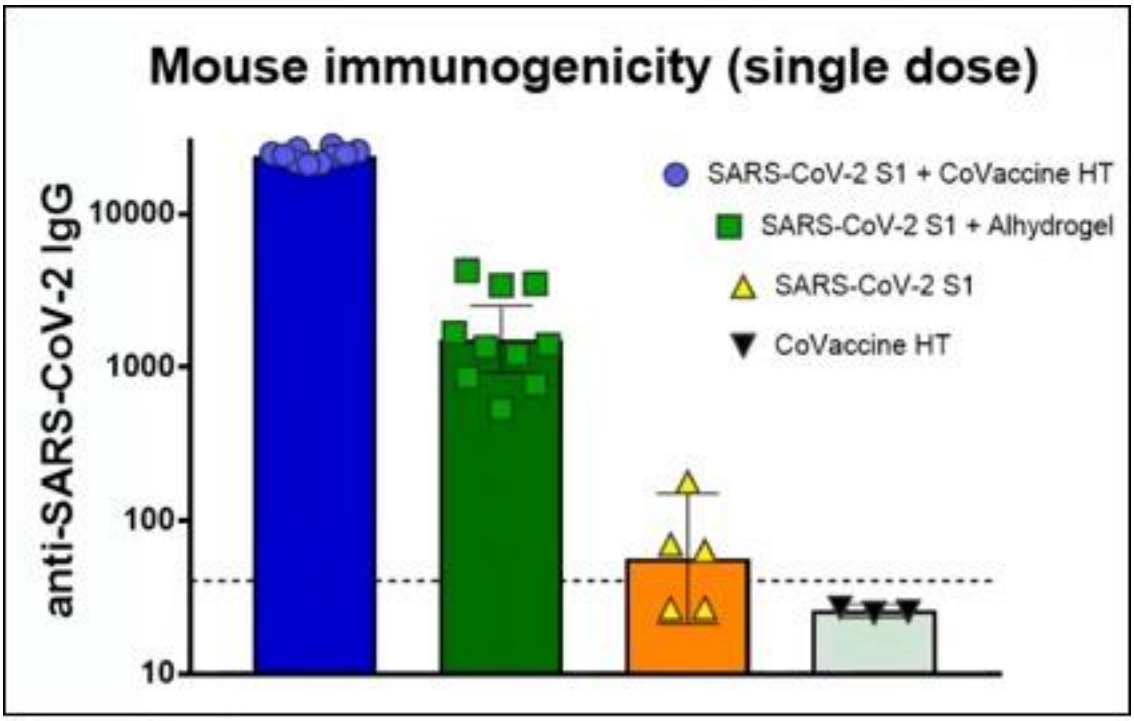
In April 2020, Soligenix announced positive results for Cycle 2 of the Phase 3 FLASH clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL) showing that continued treatment out to 12 weeks results in increased efficacy as shown by a 40% responder rate ($P<0.0001$ compared to both placebo and six-week treatment data). These data show that treatment with SGX301 is efficacious when compared to a placebo treatment, and that continued treatment results in better outcomes. The safety profile of SGX301 continues to show that the drug is safe and well tolerated. We anticipate results from Cycle 3 of the trial in the fourth quarter of 2020.

The FLASH (Fluorescent Light Activated Synthetic Hypericin) trial is 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). In Cycle 1, patients were randomized 2:1 (n=116 for SGX301; n=50 for placebo) to receive twice weekly treatment of either 0.25% SGX301 or placebo (an ointment with the same light exposure as for SGX301) for six weeks, with treatment response determined at the end of the eighth week. In Cycle 2, a total of 155 patients received 0.25% SGX301 on their target lesions (110 receiving 12 weeks of SGX301 and 45 receiving six weeks of placebo treatment followed by six weeks of SGX301 treatment), and for those that decided to continue in the trial there was a third treatment cycle where 0.25% SGX301 was applied to all of the patient's lesions.

Coronavirus Vaccine Candidate Shows Promise in Preclinical Studies

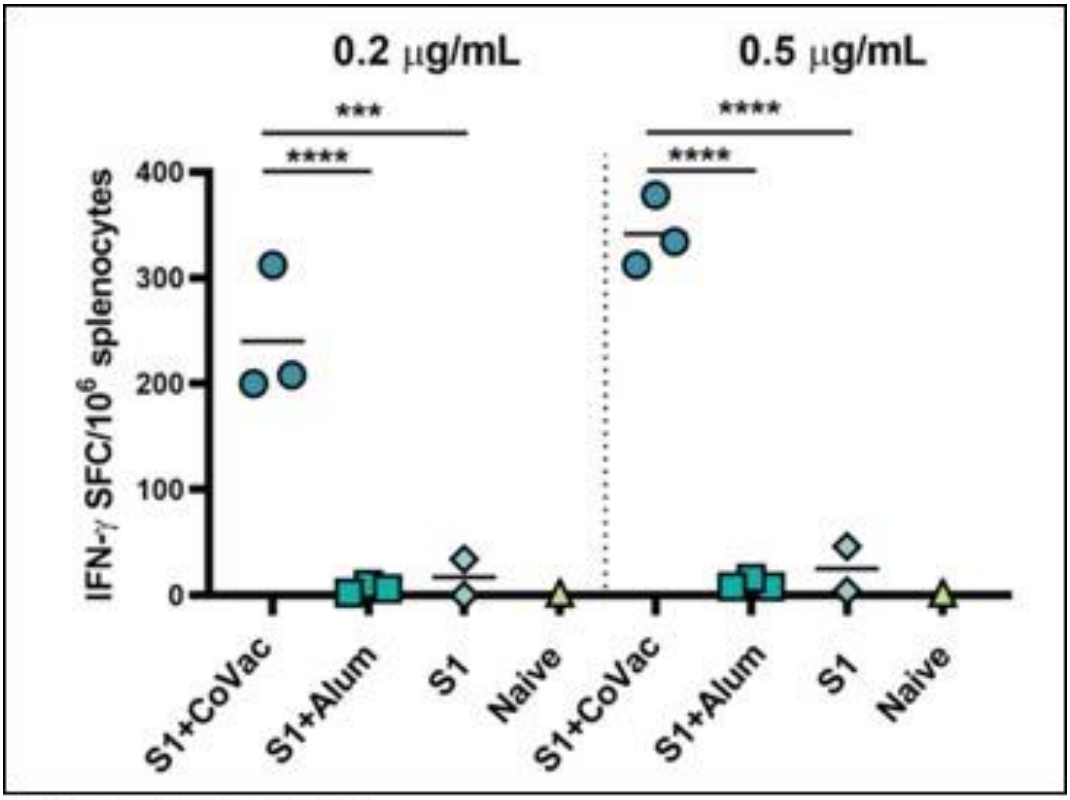
On July 28, 2020, Soligenix announced the publication of a preclinical study of the company's CiVax™ program, which is a vaccine against SARS-CoV-2, the virus responsible for COVID-19 (Haun *et al.*, 2020). The vaccine utilizes the spike protein injected in combination with the CoVaccine HT™ adjuvant. The CoVaccine adjuvant is able to stimulate both humoral (antibody) and cell mediated (T cell) immunity, an important attribute as most of the vaccines farthest along in development are focused mostly on an antibody response. Please see our previous Q&A on CiVax™ for additional information.

The following figure, from the company's presentation at the 2020 MedInvest Infectious Disease and Immunology Conference (link to watch the presentation here), shows that the company's SARS-CoV-2 vaccine candidate combined with CoVaccine HT results in a very high antibody titer, particularly compared to the immunogen alone or when dosed with the adjuvant Alhydrogel (alum). It should be noted that this antibody response was seen after only a single injection.



Source: Soligenix, Inc.

In addition to a robust antibody response, the vaccine with CoVaccine HT adjuvant elicited a strong Th1-predominant cellular immune response, which is shown by the number of splenocytes that secrete interferon (IFN)-γ when exposed to SARS-CoV-2 spike protein peptide pools. The spike protein alone or with alum did not elicit a T cell response.



Source: Haun *et al.*, 2020

One of the biggest advantages of the Soligenix vaccine platform is its compatibility with thermostabilization, which allows ambient shipping and storage to temperatures as high as 40°C (104 °F). This is an important differentiator from the COVID-19 vaccines as the cold-chain doesn't need to be maintained and deliveries are not as time sensitive. This compares with the vaccine candidates that are currently in Phase 3 development that require shipping and storage at -20°C (mRNA vaccines) or 4°C (viral vector).

Soligenix will be continuing to advance both the antigen and adjuvant manufacturing efforts and performing additional nonclinical studies. The company is also pursuing a number of funding initiatives to drive the rapid scale up of manufacturing that will be required as it moves closer to clinical trials.

Financial Update

On August 14, 2020, Soligenix announced financial results for the second quarter of 2020. The company reported revenues for second quarter of 2020 of $0.5 million, compared to $1.4 million for the second quarter of 2019. The revenues included payments on a contract in support of RiVax™, the ricin vaccine candidate, and grants received to support the development of SGX943, Thermovax®, and SGX942.

R&D expenses for the second quarter of 2020 were $2.2 million, compared to $1.9 million for the second quarter of 2019. The increase was primarily due to site and patient fees for the Phase 3 clinical trials of SGX301 and SGX942. G&A expenses for the second quarters of 2020 and 2019 were $0.8 million.

As of June 30, 2020, Soligenix had approximately $11.2 million in cash and cash equivalents. From July 1, 2020 through August 10, 2020, the company issued approximately 1.3 million shares of stock through the Sales Agreement with FBR for total proceeds of approximately $3.2 million.

As of August 11, 2020, Soligenix has approximately 29.8 million shares of common stock and, when factoring in options and warrants, a fully diluted share count of 37.2 million shares.

Conclusion

The first half of 2020 was very successful for Soligenix with the positive Phase 3 results for SGX301 in CTCL. However, even with positive Phase 3 results, the stock has not responded as we would have expected and has been essentially flat since March 2020 even while the overall biotech sector has gone up tremendously. We don't believe this will last as investors begin to appreciate the opportunity for SGX301 and how it is likely to be used as front-line therapy for a large percentage of CTCL patients. We don't anticipate the disconnect between the share price and our valuation to continue for the whole year, particularly as we get closer to the data readout for SGX942 in the fourth quarter of 2020 and we view the current share price as an excellent entry point for investors. Our current valuation remains at $12 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$4.6	$0.9	$0.5	$1.1	$1.1	$3.6	$4.5	$4.5
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.0
SGX942	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$4.6**	**$0.9**	**$0.5**	**$1.1**	**$1.1**	**$3.6**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.4	$0.9	$0.9	$3.0	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.1**	**$0.2**	**$0.2**	**$0.6**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*28.1%*	*18.2%*	*18.2%*	*17.5%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.7	$2.2	$2.4	$2.5	$9.8	$10.0	$12.0
General & Administrative	$3.5	$0.9	$0.8	$0.9	$1.0	$3.6	$10.0	$18.0
Other Expenses	$0.0	$5.0	$0.0	$0.0	$0.0	$5.0	$0.0	$0.0
Operating Income	($10.5)	($8.5)	($2.8)	($3.1)	($3.3)	($17.7)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.0	$0.1	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($8.4)**	**($2.8)**	**($3.1)**	**($3.3)**	**($17.5)**	**($19.0)**	**($12.3)**
Net Taxes (benefit)	$0.6	($0.8)	$0.0	$0.0	$0.0	$0.8	$0.0	$0.0
Tax Rate	*6.1%*	*9.9%*	*0.0%*	*0.0%*	*0.0%*	*4.8%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($7.6)**	**($2.8)**	**($3.1)**	**($3.3)**	**($16.7)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.10)**	**($0.10)**	**($0.11)**	**($0.60)**	**($0.58)**	**($0.34)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.9	30.0	30.0	27.6	33.0	36.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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