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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Publication on Immune Correlates for RiVax®…

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 (05/20/20)	$1.59
Valuation	**$12.00**

OUTLOOK

On May 11, 2020, Soligenix, Inc. (SNGX) announced the publication of immunogenicity studies for RiVax®, the company's vaccine to protect against ricin exposure. The studies showed a novel means to correlate immune response to RiVax® with survival, an important milestone as the company advances the vaccine toward potential approval through the FDA's 'Animal Rule'.

The company has already reported positive Phase 3 results for the SGX301 in cutaneous T cell lymphoma (CTCL), and we anticipate Phase 3 data for SGX942 for the treatment of oral mucositis in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy in the fourth quarter of 2020.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.67**
One-Year Return (%)	**135.56**
Beta	**1.10**
Average Daily Volume (sh)	**924,609**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**16**
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	**-2.7**
P/E using 2019 Estimate	**-7.8**

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	1.1 E	1.1 E	1.1 E	4.4 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	-$0.11 E	-$0.12 E	-$0.12 E	-$0.65 E
2021					-$0.63 E
2022					-$0.37 E

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WHAT'S NEW

Business Update

New Publication on RiVax®

On May 11, 2020, Soligenix announced a publication on immunogenicity studies for RiVax®, the company's heat stable ricin vaccine, that showed correlates between immune protection and survival in mice. RiVax® is one of the company's vaccine candidates being developed to protect against potential ricin exposure. Ricin toxin (RT) is one of the most lethal toxins known. It is a protein produced by the castor bean plant that is composed of two subunits, and once it enters a cell it incapacitates protein production through ribosome inhibition, which leads to cell death. RT can be lethal whether it is ingested orally or inhaled, although it is more potent through the inhalation route.

Soligenix has developed a vaccine that is a recombinant version of one of the RT subunits with two mutations that render it nontoxic. Antibodies induced through immunization with RiVax® result in protection from a lethal dose of aerosolized RT in rhesus macaques (Roy *et al*., 2015) and the vaccine was shown to be safe and well tolerated in Phase 1 studies in healthy volunteers (Vitetta *et al*., 2006; Vitetta *et al*., 2012).

Approval for RiVax® will be pursued under the FDA's "Animal Rule", which relies upon studies conducted in animals, typically non-human primates, to gauge the effectiveness of a product candidate if testing of that product in humans would be unethical (as in the case with ricin exposure). Development of RiVax® has been supported by grants procured from the NIH (approximately $25 million worth thus far) and a contract entered into with the NIH in 2014 could potentially provide up to an additional $21.2 million. The 2016 21st Century Cures Act allowed for the issuance of a priority review voucher (PRV) upon approval of a product deemed a "medical countermeasure", for which RiVax® would certainly apply. PRVs are fully transferrable and recently multiple PRVs have sold for approximately $100 million each.

The new article titled "A Multivariate Model Combining Endpoint and Epitope-specific Antibody Responses as a Correlate of Protection to Ricin Toxin" has been submitted to the journal *Vaccine* and a preprint is available (Van Slyke *et al*., 2020). The article describes how a multivariate model that combines data from pre-challenge serum epitope endpoint titers (EPT) and values derived from an epitope profiling immune-competition capture (EPICC) can be utilized to predict the vaccine-mediated immunity against ricin toxin in mice. These data are important as the company works toward approval of RiVax® through the FDA Animal Rule, as immunogenicity correlations between animal models and humans must be established.

Increased Efficacy with Continued Treatment in Phase 3 Trial of SGX301

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.

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.

The company previously reported a statistically significant treatment response in the Composite Assessment of Index Lesion Score (CAILS) primary endpoint assessed at 8 weeks for Cycle 1 with 16% of patients receiving SGX301 responding compared to only 4% receiving placebo responding (*P*=0.04). The increased responder rate along with a highly significant P value for Cycle 2 is a very encouraging sign, and we believe this sets up SGX301 to be a front-line therapy for a number of CTCL patients.

The most important takeaways for investors regarding the use of SGX301 in CTCL is that the treatment is clearly having a positive effect in terms of reducing lesion severity (any by extension, lesion symptoms), and that these positive effects are being seen in a relatively short period of time (as early as six weeks) with continued improvement with ongoing treatment. In addition, SGX301 is safe and well tolerated, which is in stark contrast to a number of other CTCL therapies (see our previous report on the Cycle 1 data for an overview of other CTCL treatments). We believe these data position SGX301 to be a likely front-line therapy option for a large percentage of CTCL patients.

Data for Phase 3 Trial of SGX942 in Oral Mucositis Expected in 4Q20

Soligenix is currently conducting the Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial of SGX942 for the treatment of oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. Due to the uncertainty surrounding the ongoing coronavirus epidemic, Soligenix has announced that an additional 25 patients will be enrolled in the trial. The additional patients are being added to the study in order to maintain the statistical integrity of the trial in case there are patients that drop out prior to completion of the study due to the coronavirus epidemic.

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, which increased the study sample size from 190 to 260 subjects. The company has achieved the target enrollment of 260 patients, however with the additional 25 patients we now predict that enrollment will complete and topline results will be announced in the fourth quarter of 2020.

Licenses Novel Adjuvant for Coronavirus Vaccine

On Apr. 16, 2020, Soligenix announced that it has licensed CoVaccine HT™, a novel vaccine adjuvant, from BTG Specialty Pharmaceuticals (a division of Boston Scientific) for use in vaccines against SARS-CoV-2, the cause of COVID-19, and pandemic influenza. CoVaccine HT enhances both cell-mediated and humoral (antibody-mediated) immunity. It has also been shown to target a Th1 response, which is considered important for coronaviruses.

Soligenix has previously shown the utility of CoVaccine HT in its filovirus vaccine program to develop vaccines against Ebola and Marburg viruses. Using CoVaccine HT, the company reported 100% efficacy in protecting rhesus macaques from Ebola, a model in which other adjuvants fail completely.

Soligenix's vaccine technology is based on using protein subunits combined with an adjuvant to increase the immune response. In addition, Soligenix has technology that allows for the thermostabilization of subunit protein vaccines to allow them to be stored and shipped at ambient temperatures. Since population-wide vaccination may be necessary to prevent extended economic disruption from COVID-19, the ability to not need refrigeration is likely to be a big advantage.

Since the company has previously produced other vaccines for different virus targets, the manufacturing platform is already in place. Importantly, this expression system produces a stable pattern of

glycosylation, which is vital to eliciting a proper immune response. Initial immunogenicity studies are ongoing and we expect manufacturing protocols to be implemented to produce sufficient quantities of antigen for the vaccine. Since protein subunit vaccines are relatively safe, human clinical trials should be able to commence relatively quickly. We expect additional guidance on timelines over the next few months.

Financial Update

On May 15, 2020, Soligenix, Inc (SNGX) announced financial results for the first quarter of 2020. The company reported revenues of $0.9 million for the first quarter of 2020 compared to $1.1 million for the first quarter of 2019. The revenues are derived from a contract in support of RiVax® and grants to support the development of SGX943 for the treatment of emergent and/or antibiotic resistant infectious diseases, ThermoVax®, and the assessment of SGX942 in juvenile animals.

Net loss for the first quarter of 2020 was $7.6 million, or $0.32 per share, compared to a net loss of $1.6 million, or $0.09 per share, for the first quarter of 2019. The increase was mostly due to the issuance of $5 million of common stock as a milestone payment triggered by the successful Phase 3 clinical trial results of SGX301 for the treatment of CTCL. R&D expenses were $2.7 million in the first quarter of 2020 compared to $1.6 million for the first quarter of 2019. G&A expenses were $0.9 million for the first quarter of both 2020 and 2019.

As of March 31, 2020, Soligenix had approximately $7.2 million in cash and cash equivalents. This does not include the approximately $840,000 that the company received in May 2020 through the New Jersey Technology Business Tax Certificate Transfer Program. As of May 8, 2020, Soligenix had approximately 26.6 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 34.0 million shares.

Conclusion

Thus far, 2020 has been a very successful year 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 E	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	$1.1	$1.1	$1.1	$4.2	$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**	**$1.1**	**$1.1**	**$1.1**	**$4.2**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.9	$0.9	$0.9	$3.5	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.2**	**$0.2**	**$0.2**	**$0.7**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*18.2%*	*18.2%*	*18.2%*	*16.5%*	*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	$0.9	$0.9	$1.0	$3.7	$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)	($2.9)	($3.1)	($3.3)	($17.8)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.1	$0.1	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($8.4)**	**($2.9)**	**($3.1)**	**($3.3)**	**($17.6)**	**($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)**	**($2.9)**	**($3.1)**	**($3.3)**	**($16.7)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.64)**	**($0.63)**	**($0.37)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.6	26.8	27.0	26.0	30.0	33.0

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

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HISTORICAL STOCK PRICE



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