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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Developing Coronavirus Vaccine…

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 (03/31/20)	$1.50
Valuation	**$12.00**

OUTLOOK

On March 30, 2020, Soligenix, Inc. (SNGX) announced financial results for the fourth quarter and full year 2019 and provided a business update. The company recently announced positive topline results from the Phase 3 FLASH trial of SGX301 in patients suffering from cutaneous T cell lymphoma (CTCL). In addition, Soligenix's collaboration with the University of Hawaii at Manoa will be expanded to assess potential vaccines against coronaviruses, including SARS-CoV-2. The vaccine technology allows the immunization of children, the elderly, and those who are immunocompromised, groups that are typically excluded from using viral vector vaccines. Lastly, due to uncertainty surrounding the coronavirus epidemic, the company will be enrolling 25 additional subjects into the Phase 3 trial of SGX942 in patients with oral mucositis and because of this topline results will be released in the fourth quarter of 2020.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.67**
One-Year Return (%)	**70.46**
Beta	**0.89**
Average Daily Volume (sh)	**567,408**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$36**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-12.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-4.7**
P/E using 2019 Estimate	**-8.1**

Risk Level	**High**
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	1.1 E	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	-$0.11 E	-$0.11 E	-$0.12 E	-$0.12 E	-$0.45 E
2021					-$0.63 E
2022					-$0.37 E

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Business Update

Developing Coronavirus Vaccines

On March 23, 2020, Soligenix, Inc. (SNGX) announced an expansion of the ongoing collaboration with the University of Hawaii at Manoa to develop potential coronavirus vaccines, including one against SARS-CoV-2 to prevent COVID-19.

Soligenix has performed extensive work on vaccines targeting other viruses in collaboration with the University of Hawaii, the University of Colorado, and Hawaii Biotech, Inc. That work has demonstrated efficacy in using a surface protein from other viruses (e.g., ebola), adjuvanting them, and thermostabilizing them. SARS-CoV-2, and other betacoronaviruses, have spike proteins on the surface that aids in viral entry and antibodies to that protein could prevent viral entry.

There are a number of technologies being used to develop vaccines targeting SARS-CoV-2, including nucleic acid vaccines and those involving viral vectors. There are currently no FDA approved vaccines that are RNA- or DNA-based, thus there are questions about whether those approaches will be successful. A number of viral vector vaccines are contraindicated for immunocompromised individuals along with pregnant women and the very young and very old, thus their use could be limited.

Soligenix's 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, 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. 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.

Positive Topline Results for SGX301 Phase 3 Trial in CTCL

On March 19, 2020, Soligenix announced positive topline results for the Phase 3 clinical trial of SGX301 in patients with cutaneous T cell lymphoma (CTCL). 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).

The trial consisted of three treatment cycles, with each cycle lasting eight weeks. Each study subject had three target lesions treated during the trial. 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, all subjects received 0.25% SGX301 on their target lesions, 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 results showed 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). A preliminary analysis of the open label Cycle 2 suggests that the treatment effect increases after 12 weeks of treatment with

SGX301, as the blinded data suggests more than a 35% response rate for SGX301 treatment. The full topline results for Cycle 2 will be announced in June 2020.

Soligenix had two lead investigators on the call and members of the Cutaneous Lymphoma Foundation to give their opinions of the data and what it might mean for patients:

- Dr. Brian Poligone (the Director of the Rochester Skin Lymphoma Medical Group in Fairport, NY and an Investigator for the FLASH trial) stated that the response rates seen were very encouraging. Most CTCL treatments are carried out over a much longer time period, so to see positive results at only six weeks is very promising. In addition, the fact that response rates seem to be improving with increased treatment length is a very encouraging sign. Lastly, Dr. Poligone stressed how important management of side effects and toxicities is for CTCL since treatments can go on for years or even decades.

- Dr. Ellen Kim (Medical Director at the Dermatology Clinic at the Perelman Center for Advanced Medicine and an investigator for the FLASH trial), who has treated CTCL patients for 18 years, was also on the call and stated she expects using SGX301 in approximately 30-50% of her patients and that it would generally be used in roughly the same percentage, if not higher, at other medical centers that treat CTCL.

- Susan Thornton (CEO of the Cutaneous Lymphoma Foundation) stated that the results presented by Soligenix were great news for patients, since they are looking for a treatment that is effective but has the least amount of side effects. Unfortunately, many of the currently available therapies don't work for all patients, don't work for an extended period of time, are difficult to access due to being used off-label, or have serious side effects. Thus, having another treatment option that is effective with limited side effects would be an excellent opportunity for individuals living with CTCL.

Importantly, there were no safety signals and the treatment was well tolerated. The safety of SGX301 is a clear differentiator from currently available therapies as its mechanism of action is not associated with DNA damage, which is contrast to currently available phototherapies that include risk factors such as melanoma and other malignancies, skin damage, and premature skin aging.

How does SGX301 Compare to Other CTCL Treatments?

Currently, there are no approved first line therapies for early stage CTCL, thus if its approved, SGX301 would be the first and only. Based upon the positive results, excellent safety profile, and enthusiasm from CTCL clinicians, we would expect SGX301 to be used as a front-line therapy in at least 1/3rd of patients. Other therapies that are currently utilized as first-line treatments are shown below:

Topical corticosteroids – these are used off-label for a large percentage of patients as front-line therapy due to the fact that they have anti-inflammatory effects and can directly kill lymphoma cells. However, they are associated with several side effects, including thinning of the skin, acne, and hair growth. In addition, prolonged use of corticosteroids can decrease the activity of the adrenal gland, thus while they are generally considered safe to use, topical steroid therapy must be closely monitored by a cutaneous lymphoma provider.

Topical chemotherapy – chemotherapy is only used as a second-line therapy in patients that have received prior skin-directed therapy. Mechlorethamine (Valchlor®) and carmustine (BiCNU®) are generally safe when applied topically, however side effects include redness, irritation, and hyperpigmentation.

Retinoids – these are used as a second-line therapy in patients who are refractory following other therapies or who aren't able to tolerate other therapies. Retinoids are derived from Vitamin A and have been shown to kill cancer cells. Bexarotene (Targretin®), acitretin, and tazarotene gel (Tazorac®) are examples of retinoids used in treating CTCL. The most common side effects are skin irritation, redness,

itching, and burning. In addition, skin that is treated with topical retinoids should be kept out of the sun and away from other sources of ultraviolet (UV) light.

PUVA phototherapy – Psoralens are photosensitizing agents derived from plants. They are taken orally prior to exposure to UVA light ("PUVA"), with the UV light causing the psoralen to become toxic to the cancer cells. PUVA is not approved for treating CTCL but is used off-label. Side effects include stomach upset and nausea for oral psoralens, with long-term complications from PUVA therapy being the development of skin damage (wrinkles, sun spots) and even skin cancers.

NB-UVB/BB-UVB – UVB phototherapy is effective for thinner skin lesions, however it is not approved for CTCL. It uses UVB light, either narrow band (NB) or broad band (BB), in which the affected areas are exposed to the light for two to three times per week, with gradual increases in dose over time. It typically takes four to six months to see an improvement. Side effects include sun burn, temporary redness, or burning of the skin with long term treatment potentially increasing the risk for skin cancer.

Phase 3 Data for Oral Mucositis Study in 4Q20

Due to the uncertainty surrounding the ongoing coronavirus epidemic, Soligenix has announced that an additional 25 patients will be enrolled in the ongoing 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. 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. Thus, we now anticipate topline results to be reported in the fourth quarter of 2020.

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.

We believe the DMC's recommendation was indicative of a promising signal in the primary endpoint. The increase in study sample size was required to account for any potential variability observed in the Phase 3 trial that differs from the trials original design assumptions. In addition, no safety concerns were reported by the DMC based on the interim analysis.

Financial Update

On Mar. 30, 2020, Soligenix announced financial results for 2019. The company reported $4.6 million in revenues in 2019, compared to $5.2 million in 2018. The revenues are derived from a contract in support of RiVax® along with grants to support the development of SGX301 and SGX942. R&D expenses were $8.1 million in 2019, compared to $6.8 million in 2018. The increase was due to the expansion of the SGX942 Phase 3 clinical trial and the ongoing Phase 3 clinical trial of SGX301. G&A expenses were $3.4 million in 2019, compared to $3.0 million in 2018. The increase was related to increased employee compensation, additional employee positions, and expenses related to the UK R&D tax credit.

As of mid-March Soligenix had approximately $7.6 million in cash and cash equivalents, which does not include the expected sale of the New Jersey net operating loss carryovers, the United Kingdom tax incentive receivable of approximately $1 million, or the non-dilutive grant funding. In addition, the company has an ATM agreement in place with B. Riley FBR. We estimate the company has sufficient capital to fund operations through the end of 2020, and the company will be assessing various commercialization and/or partnership outcomes for SGX301 while preparing the NDA filing.

As of Mar. 23, 2020, Soligenix had approximately 25.8 million shares of common stock outstanding and when factoring in stock options and warrants there is a fully diluted share count of approximately 33.5 million.

Conclusion

We are glad to see Soligenix apply the company's vaccine technology to the ongoing coronavirus pandemic, and we look forward to additional updates on the program in the coming quarters. The technology has a number of advantages over other vaccines in development, and given the safety of protein subunit vaccines we expect it will enter human testing relatively quickly.

The results announced by Soligenix for the CTCL Phase 3 trial are a clear win for the company, investors, and patients. While we would have expected a bit more of a positive reaction in the stock price, it was likely held back by the current market environment and waiting for the Phase 3 results from the OM trial, which we now expect in the fouth quarter of 2020. Our current valuation is $12 per share.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 E	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	$1.1	$1.1	$1.1	$1.1	$4.4	$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**	**$1.1**	**$1.1**	**$1.1**	**$1.1**	**$4.4**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.9	$0.9	$0.9	$0.9	$3.6	$3.7	$8.0
Gross Income	**$1.1**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*18.9%*	*18.2%*	*18.2%*	*18.2%*	*18.4%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.0	$2.2	$2.4	$2.5	$9.1	$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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10.5)	($2.7)	($2.9)	($3.1)	($3.3)	($12.0)	($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)**	**($2.6)**	**($2.9)**	**($3.1)**	**($3.3)**	**($11.8)**	**($19.0)**	**($12.3)**
Net Taxes (benefit)	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*6.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($2.6)**	**($2.9)**	**($3.1)**	**($3.3)**	**($11.8)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.11)**	**($0.11)**	**($0.12)**	**($0.12)**	**($0.45)**	**($0.63)**	**($0.37)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	25.0	26.0	26.0	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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