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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Update and Q&A on COVID-19 Vaccine Candidate CiVax™…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301, SGX942, and CiVax, SNGX is valued at $15.00 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 (09/11/20)	$1.96
Valuation	**$15.00**

OUTLOOK

On September 10, 2020, Soligenix, Inc. (SNGX) held a webinar to provide an update on the company's COVID-19 vaccine candidate CiVax™. CiVax is comprised of a recombinant version of the spike (S) protein that is produced in insect cells, which results in a stable glycosylation pattern. Soligenix previously licensed CoVaccine HT™, an adjuvant that stimulates both antibody and cell-mediated immunity. In addition, the company's thermostabilization technology, ThermoVax®, allows for the vaccine to be lyophilized, which can increase stability even at elevated temperatures. This is in stark contrast to the current leading COVID-19 vaccine candidates, some of which require storage at -20ºC or -70ºC, which may lead to logistical issues for distributing vaccines in remote locations. We anticipate the company announcing non-human primate efficacy data before the end of 2020 and a Phase 1 clinical trial could initiate in the next 6-9 months, although this is dependent on non-dilutive funding.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$0.87**
One-Year Return (%)	**117.78**
Beta	**1.23**
Average Daily Volume (sh)	**406,155**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$59**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
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

Business Update

Update on COVID-19 Vaccine Candidate CiVax™

On September 10, 2020, Soligenix, Inc. (SNGX) held a webinar to provide an update on the COVID-19 vaccine landscape and the company's COVID-19 vaccine candidate CiVax™. According to the World Health Organization (WHO), as of Sep. 9, 2020 there are currently 35 COVID-19 vaccine candidates in clinical trials and 145 in preclinical development (WHO). There are a number of different platforms being evaluated, with each platform having its strengths and weaknesses. These platforms include live attenuated replicating viruses, nucleic acid (mRNA or DNA), non-replicating viral vectors, and protein subunit.

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 includes the CoVaccine HT™ adjuvant, which Soligenix recently licensed from BTG-Boston Scientific. CoVaccine HT has previously been shown to induce both humoral (antibody) and cell-mediated immunity. Lastly, Soligenix's thermostabilization platform, ThermoVax®, 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.

With so many COVID-19 vaccines in development, there are a number of factors that will help to differentiate the various vaccine candidates, including:

- Safety – What kind of side effects does the vaccine cause?
- Storage/distribution requirements – How will the vaccine need to be stored (e.g., room temp, 4ºC, -20ºC, -70ºC)?
- Dosing requirements – How many doses will be required to achieve optimal immunity?
- Manufacturing requirements – How many doses can be produced? How quickly can they be produced?
- Durability of response – How long will immunity last? Will booster shots be required and if so, how often?

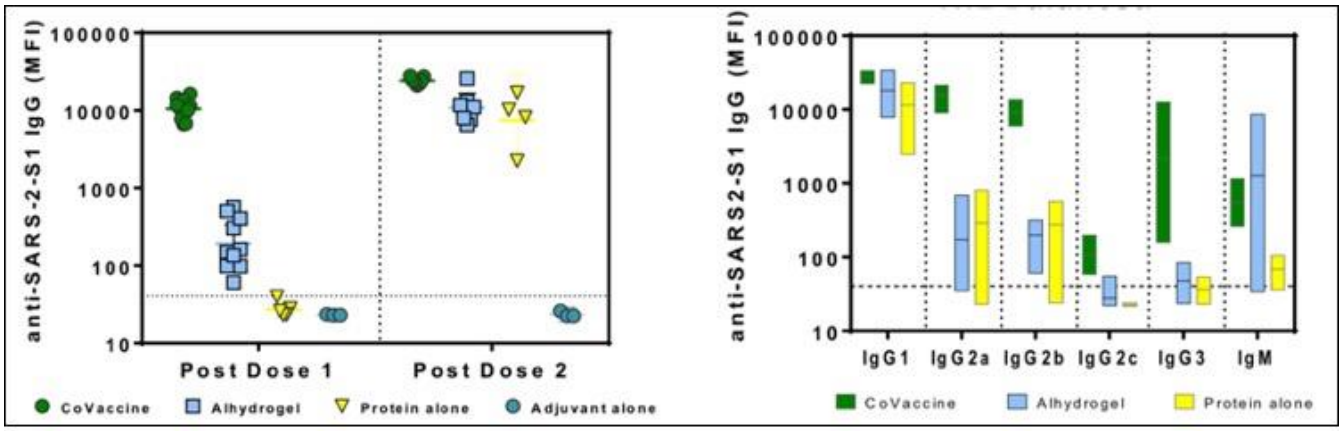
While it will take time before we know the answers to all these questions, some of them are becoming clearer as different vaccine modalities advance in development. The following slide gives an overview for what we know regarding the various vaccine platforms in development, with the protein subunit platform, particularly in a stable, lyophilized formulation, having some clear advantages.

Parameter / Platform	Protein (Soligenix / UH) *	Protein (NovaVax)	rVSV	chAd (AstraZeneca)	Ad26 (Janssen)	RNA (Moderna/ BioNtech)
Ambient storage	✓	?	×	×	×	×
Immune compromised populations?	✓	✓	×	×	×	?
Repeat vaccination possible?	✓	✓	×	Limited	Limited	✓
Single dose regimen?	?	?	?	×	×	×
Simple manufacturing / Scale Out	✓	?	×	×	×	✓
No risk of genomic integration	✓	✓	×	×	×	✓
Single vial formulation	✓	×	?	✓	✓	✓
Used in other approved vaccines (reduces regulatory risk)	✓	✓	✓ (Ebola)	×	✓ (Ebola)	×

*uses a stably transformed expression cell line with protein specific affinity purification for antigen production, combined with a novel, clinically proven, adjuvant (CoVaccine), both of which will be combined with GRAS excipients to yield a thermostabilized formulation

Source: Soligenix, Inc.

A proof of concept study of CiVax and CoVaccine HT in mice showed that a single dose resulted in a robust antibody response that was similar to two doses of spike protein and alhyrogel (alum) adjuvant (lower left figure). This immune response was Th1 biased, as shown by the robust titer of IgG2a and IgG2b antibodies (lower right figure).



Source: Soligenix, Inc.

Soligenix is also developing CiVax with a proprietary antigen, the full-length spike protein with targeted mutations to lock it in the pre-fusion configuration. This antigen is also capable of inducing a Th1-biased immune response when injected with CoVaccine HT. Further development of this vaccine formulation will be possible with government funding.

In addition to discussing CiVax, the company also mentioned that dusquetide (SGX-942), which is currently being studied in a Phase 3 clinical trial in oral mucositis, with results expected in the fourth quarter of 2020, could potentially be used as a treatment for SARS-CoV-2 infection. Dusquetide would most likely be studied in both hospitalized patients, to test whether it could prevent progression to severe respiratory disease, and in severely ill patients to determine if it could decrease the fatality rate when used in conjunction with remdesivir. Soligenix is continuing to pursue non-dilutive funding to potentially advance dusquetide as a COVID-19 treatment.

Q&A on CiVax

At the end of the CiVax webinar, Soligenix management answered a few questions, however time ran out before all questions could be answered. The following Q&A covers some questions that we had that were not covered during the webinar, with answers provided by Dr. Oreola Donini (OD), Chief Scientific Officer, Dan Ring (DR), VP Business Development and Strategic Planning, and Dr. Chris Schaber (CS), President and CEO.

DB: When could you start a Phase 1 human study with CiVax?
OD: As Chris noted during the call, a Phase 1 study would be dependent on additional dedicated funding. However, assuming funding, a Phase 1 study could potentially start within 6-9 months. We also expect that subsequent studies would be relatively rapid, leveraging the immunogenicity readouts from the other COVID-19 vaccine Phase 3 trials that are ongoing. Again, this would be contingent on additional funding, namely through non-dilutive sources as we have traditionally done with our Public Health Solutions segment.

DB: How do you envision positioning CiVax in an already very crowded market?
DR: The need for a COVID-19 vaccine worldwide means that there is an extensive market that no single vaccine will be able to fill within a couple of years. As well, it is expected that protection will need to be maintained for a couple of years to reduce virus circulation and achieve herd immunity. The current expectation is that this will require semi-annual or annual vaccinations. As a consequence of its broad applicability and expected safety profile, CiVax should be well-positioned to capitalize on any market gaps or failures among the lead products. Moreover, the heat stabilized format of the vaccine requiring only water for

injection for reconstitution at the clinical site should also make it easily distributable, including to remote areas both within and outside the United States.

DB: How quickly can you get to a Phase 3 study with CiVax?
OD: As you can imagine there are a number of moving pieces here that make it difficult to predict how quickly the development timeline could move today; however, I think it's safe to say that with government support, we have the potential to move much quicker than with a traditional development timeline, as we have seen occurring under the WARP speed initiative. Again, I just want to reiterate what Chris said earlier. Although we believe there will be a need for multiple approved vaccines in the fight against COVID-19 and we have a unique heat stable vaccine approach that has garnered potential interest, we currently view the CiVax program as we do our other development programs in our Public Health Solutions segment, i.e., the current focus is pursuing and securing non-dilutive funding sources to advance it.

DB: How does heat stabilization work? What other vaccines can it be used for?
OD: Heat stabilization works by removing water from the vaccine preparation. Water is able to facilitate a number of chemical reactions which lead to vaccine degradation. We remove the water by using lyophilization (also known as freeze drying). The key to this technology is finding the correct excipients for a given vaccine to stabilize its structure during the freeze drying process. We also emphasize the need to reconstitute the vaccine with water for injection as this removes key logistical constraints in distributing a vaccine. Our technology is primarily relevant to subunit protein vaccines, although we could explore other applications. In the context of protein vaccines – it is not only important to stabilize the antigen, meaning the protein, but also the adjuvant.

DB: Has CoVaccine been FDA approved?
OD: This is a very important question, and as you know, adjuvants alone do not receive regulatory approval, but are approved as integral constituents of a vaccine formulation. CoVaccine has not been part of an FDA approved vaccine, but it has been tested in Phase 1 and Phase 2 clinical studies under the auspices of the MHRA in the UK.

DB: Can you describe some of the logistical constraints anticipated around vaccine distribution and how you will address them.
DR: A number of logistical constraints have become apparent in the recent weeks. Among these are:
1. Cold chain requirements – which we will obviously address with our heat stabilized formulation.
2. Reagent restrictions – for instance some adjuvants use key reagents that are in limited supply while the CoVaccine ingredients are commonly available (e.g, from olive oil). In fact, CiVax is expected to be manufactured without the need for animal derived products.
3. Syringe availability – while CiVax would have to be parenterally delivered, we believe it can be injected with a needle free device as well as a standard syringe, potentially alleviating supply constraints.
4. Point of use mixing – other protein vaccines use an adjuvant which must be added at point of use typically from a second vial. This means there is a logistical distribution supply chain (and stability concerns) for both the antigen and the adjuvant. In contrast, CiVax is intended to include all components within a single vial, only requiring the addition of sterile water – which is both stable and has its own wide-spread distribution network.

DB: How feasible would it be to rapidly modify CiVax if a new strain of SARS-CoV-2 were identified?
OD: Having identified the key parameters to generate a stably expressing cell line for protein production, it will be relatively straightforward to modify the system to produce different forms of the Spike protein, depending on what the specific mutations are. Certainly, we can reasonably expect downstream manufacturing (purification, formulation conditions, addition of adjuvant, thermostabilization) to remain the same. Moreover, if multiple strains were circulating, it likely would be possible to generate a multivalent vaccine able to address both versions at the same time since we've had significant success with this in our filovirus program.

DB: I know the pivotal Phase 3 program for SGX942 was not the main topic for today's discussion, but can you give any additional insights into its status?
CS: As I noted during the presentation, we remain on track to announce topline results for the Phase 3 oral mucositis program in 4Q of this year. With the positive top-line results already announced earlier in the year for our other Phase 3 study with SGX301 in CTCL, we are eager to get to the SGX942 results in the oral mucositis program, which has the potential to be a significant market opportunity and transformational for the company. As I also noted, we remain active on the business development front across these two programs as

well and believe there is the potential for partnership, but obviously cannot give any further guidance beyond that. One thing is for certain, we have some very important near-term catalysts in the back half of 2020.

Conclusion

CiVax is an exciting program for Soligenix and it has a number of advantages when compared to other COVID-19 vaccines in development, particularly the Th1-biased immune response (both humoral and cell mediated), the strong safety record of protein vaccines, the potential for only needing one dose for a robust immune response, and the heat stability that would preclude the need for cold-chain storage. We anticipate additional updates regarding the program over the next few months, particularly if the company is successful in obtaining any non-dilutive funding, as Soligenix has not traditionally advanced vaccine candidates without funding support. Adding CiVax to our model has increased our valuation from $12 to $15.

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*

HISTORICAL STOCK PRICE

Source: Zacks Small Cap Research

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