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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Provides Update on SGX301 Commercialization Plan…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301, and CiVax, SNGX is valued at $6.50 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 (01/28/21)	$1.50
Valuation	**$6.50**

OUTLOOK

On January 26, 2021, Soligenix, Inc. (SNGX) conducted a webinar to discuss SGX301, the company's lead compound that has successfully completed a Phase 3 program in cutaneous T cell lymphoma (CTCL) and for which an NDA will be filed later in 2021. Following an overview of CTCL and the results of the Phase 3 clinical trial for SGX301, the company outlined its commercialization strategy, which will consist of approximately 20 sales representatives across the U.S. that the company estimates can cover the majority of CTCL treatment centers. We anticipate the company initiating the rolling NDA submission in the second quarter of 2021 which could lead to approval in the first half of 2022 and commercial launch in the second half of 2022.

SUMMARY DATA

52-Week High	**$3.34**
52-Week Low	**$1.26**
One-Year Return (%)	**-43.18**
Beta	**1.42**
Average Daily Volume (sh)	**4,966,792**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$47**
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 (%)	**-23.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-3.5**
P/E using 2019 Estimate	**-4.9**

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	0.9 A	0.5 A	0.6 A	1.1 E	3.1 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	-$0.06 A	-$0.11 E	-$0.56 E
2021					-$0.58 E
2022					-$0.34 E

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WHAT'S NEW

Business Update

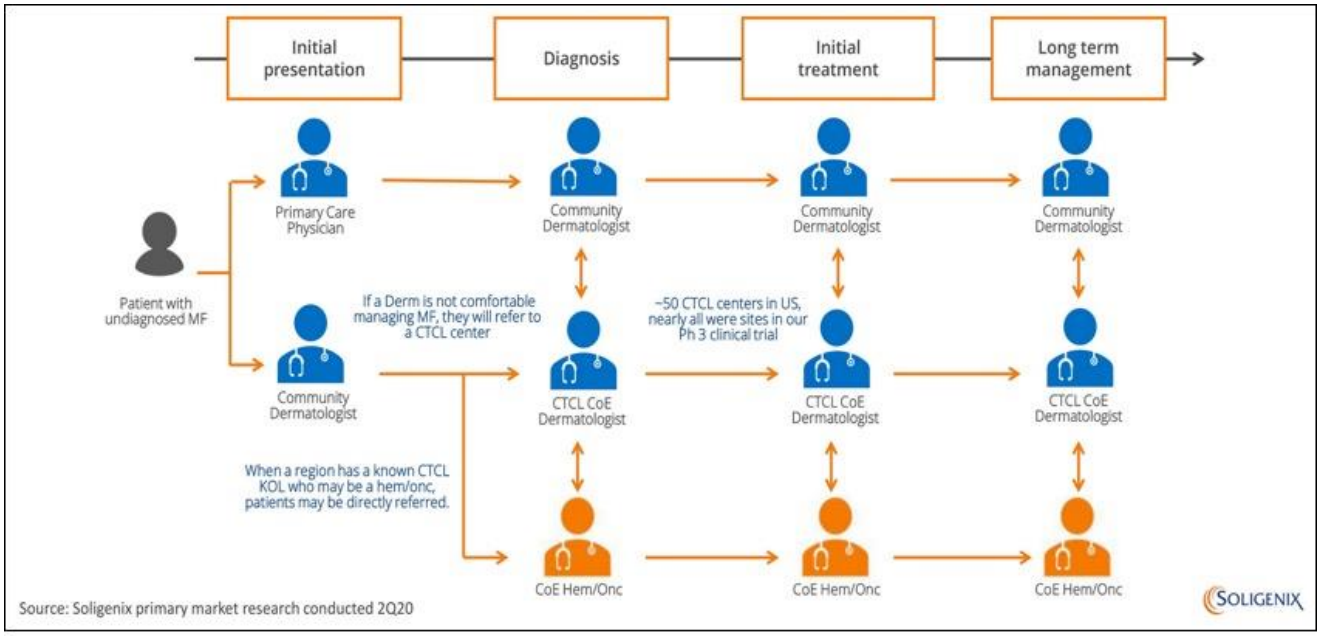
Webinar on SGX301 Outlines Company's Commercialization Plan

On January 26, 2021, Soligenix, Inc. (SNGX) held a webinar to discuss the company's plans for the commercialization of SGX301 for the treatment of cutaneous T- cell lymphoma (CTCL) that included an overview of the disease, current treatment options, and where SGX301 may fit into the treatment paradigm.

SGX301 Commercialization Plan

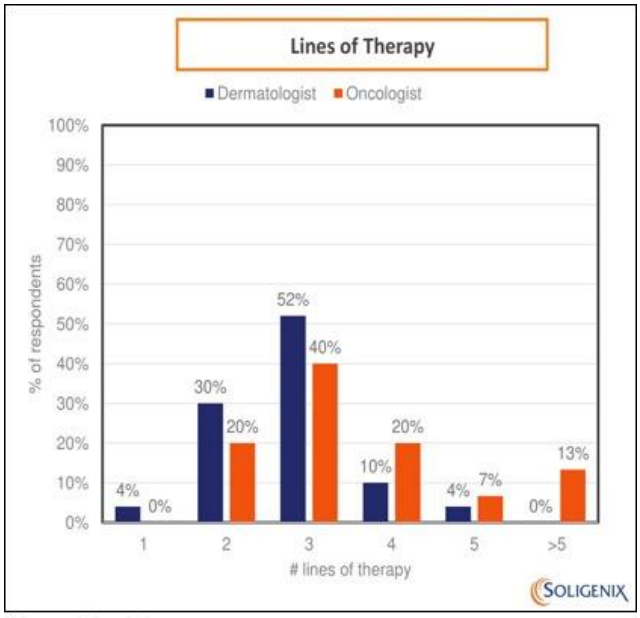
To discuss Soligenix's commercialization plan for SGX301, Mr. Michael Young (Acting Chief Marketing Officer) and Mr. Dan Ring (Vice President, Business Development) presented information on the CTCL market, data from in-depth primary market research with KOL and community dermatologists, and its plan for a sales and marketing team. Mr. Young has been involved in the launch of a number of CTCL products, thus he is very familiar with the market and it is encouraging that he is very positive about the potential for SGX301.

The following graphic shows the treatment pathway for an individual who ends up being diagnosed with CTCL. The patients will present initially to either their primary care physician or a community dermatologist. Treatment typically does not take place under the direct care of the primary care physician but is instead performed under the direction of a KOL dermatologist, at a CTCL center of excellence (CoE), for which there are approximately 50 in the U.S. The important point is that since patients typically end up under the care of a KOL dermatologist at a CoE, there isn't a need for a large sales force to market SGX301 to thousands of primary care physicians.



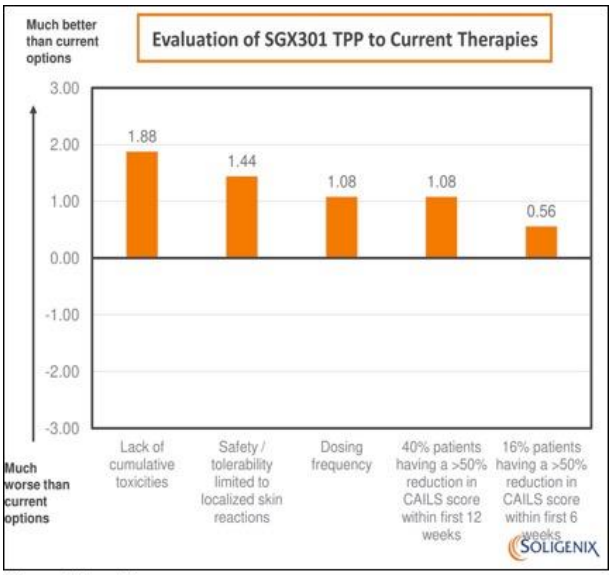
Source: Soligenix, Inc.

The company also examined how many lines of treatment an early-stage CTCL patient typically goes through, which is shown in the following chart. The chart exemplifies the fact that most patients will go through a number of different treatment options, some concomitantly rather than sequentially, which means that SGX301 will likely derive business from not just newly diagnosed patients but also patients that have been through a number of other treatment options already.



Source: Soligenix, Inc.

In research conducted with dermatologists, Soligenix inquired how the data for SGX301 compared to currently available therapies. The following chart shows how various attributes of SGX301 compare to currently available therapies in the opinion of dermatologists. Positive scores indicate that dermatologists view that attribute as being more favorable for SGX301 than for currently available treatments. For all five aspects of SGX301 (lack of cumulative toxicities, the safety and tolerability profile, the dosing frequency, and the high response rates), dermatologists believed that SGX301 was better than currently available therapies.



Source: Soligenix, Inc.

In regards to potential usage of SGX301, four out of five surveyed physicians indicated that they would likely prescribe SGX301 and, while topical steroids will likely remain a common first-line treatment, SGX301 could potentially be used in 20-30% of first-line early-stage patients. The company believes that receiving an FDA approval for first-line usage will likely drive increased usage.

Background on Light Device

For the companion light device, Soligenix has an exclusive manufacturing, distribution, and services agreement with Daavlin for its manufacture to be used specifically with SGX301. Daavlin has produced phototherapy products for more than 40 years and their products are used both in-office by dermatologists and

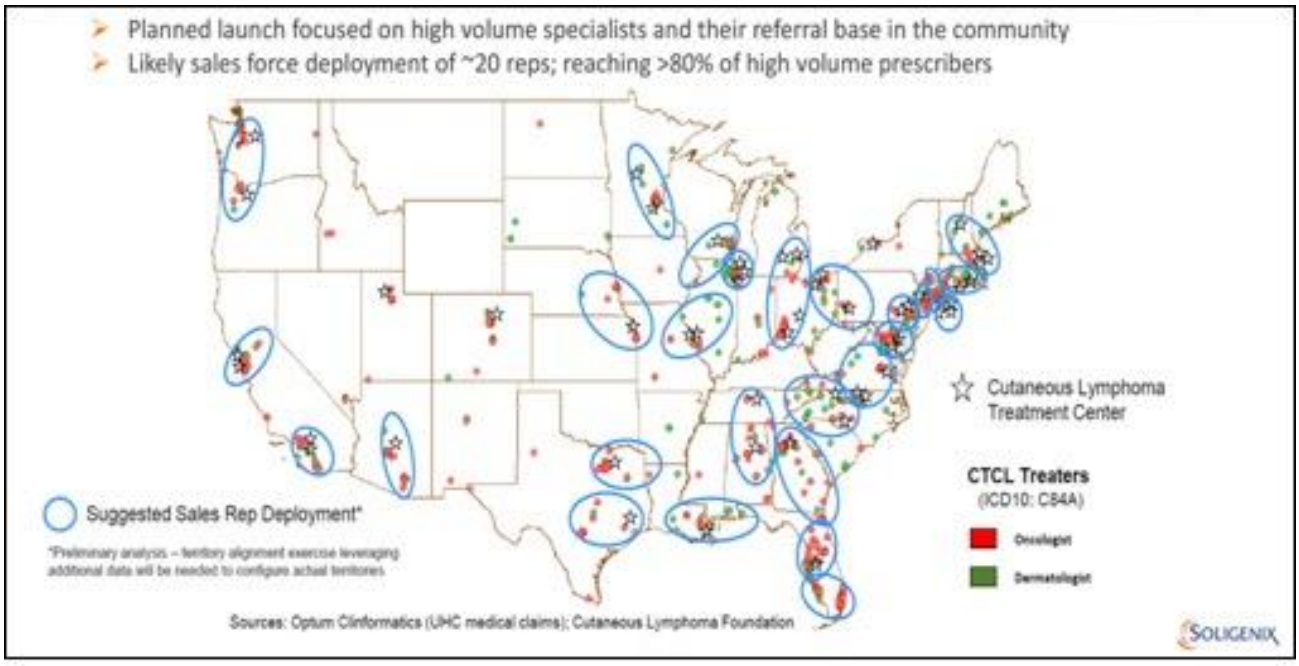
at-home by patients for treating skin disorders such as psoriasis, vitiligo, and eczema. The device being utilized with SGX301 is based on an existing light platform that Daavlin has produced and sold for >10 years and is ready for commercialization in the U.S. The Daavlin devices are already 510k approved and the light device and hypericin ointment will be viewed as a combination product by the FDA.

Soligenix is planning to sell the light device directly to physicians and then eventually to the patient for home use (likely in 12-18 months following the initial launch of the drug). Dermatologists have indicated that the anticipated unit price of approximately $5,000 is not a barrier to adoption of SGX301 and they anticipate buying the light device instead of leasing it. In addition, the probable price point for the light unit will likely fall below the threshold for a “capital expenditure”, which will preclude the necessity for a longer-term internal purchase order at target institutions.

Rather than being a hinderance to the adoption of SGX301, the light source will likely have a neutral to positive effect on uptake of the drug. First, most dermatologists are already very familiar with phototherapy devices as they are utilized for other skin conditions, thus the physicians most likely already have similar devices in their offices and exam rooms. Second, the device is convenient to use and does not require a dedicated room or a special electrical hook-up, in fact during the FLASH trial many physicians simply stored the device behind a door in an exam room for easy access. Lastly, pairing the light device with the drug should provide an additional barrier to entry for a generic down the road.

Sales and Marketing

Soligenix has decided to commercialize SGX301 on its own with a relatively small sales team of approximately 20 representatives. The following map shows the location of CTCL treatment centers in the U.S. The blue circles represent potential sales representative coverage areas, which cover the vast majority (>80%) of centers. The company estimates that there will be approximately $7 million in pre-launch expenses and <$10 million in sales and marketing expenses each year.



Source: Soligenix, Inc.

Based on current estimates, Soligenix forecasts peak sales of SGX301 in the U.S. of approximately $90 million. Competing products have generated similar sales revenues despite having inferior clinical profiles compared to SGX301. For example, VALCHOR® (mechlorethamine), which the company believes is a reasonable benchmark for what SGX301 may cost (~$3500/tube), had estimated sales of $40 million as an approved second-line treatment for CTCL while narrowband (nb) UVB therapy generated revenues of $50 million despite not being approved for treating CTCL. Included in the company’s estimates are an assumption

that patients will use one tube or jar of SGX301 per month for at least four months, however this is subject to change based on real world use of SGX301.

The company is still evaluating payer coverage as part of the market access strategy, however based on the FLASH trial demographics the payer mix is likely to be approximately 50% commercial, 40% Medicare, and 10% Medicaid. Management is confident that the drug will be covered under Medicare Part D since it is self-administered.

Lastly, the company announced the proposed proprietary brand name and logo for SGX301 as HyBryte™ and it has been submitted to the FDA for approval.



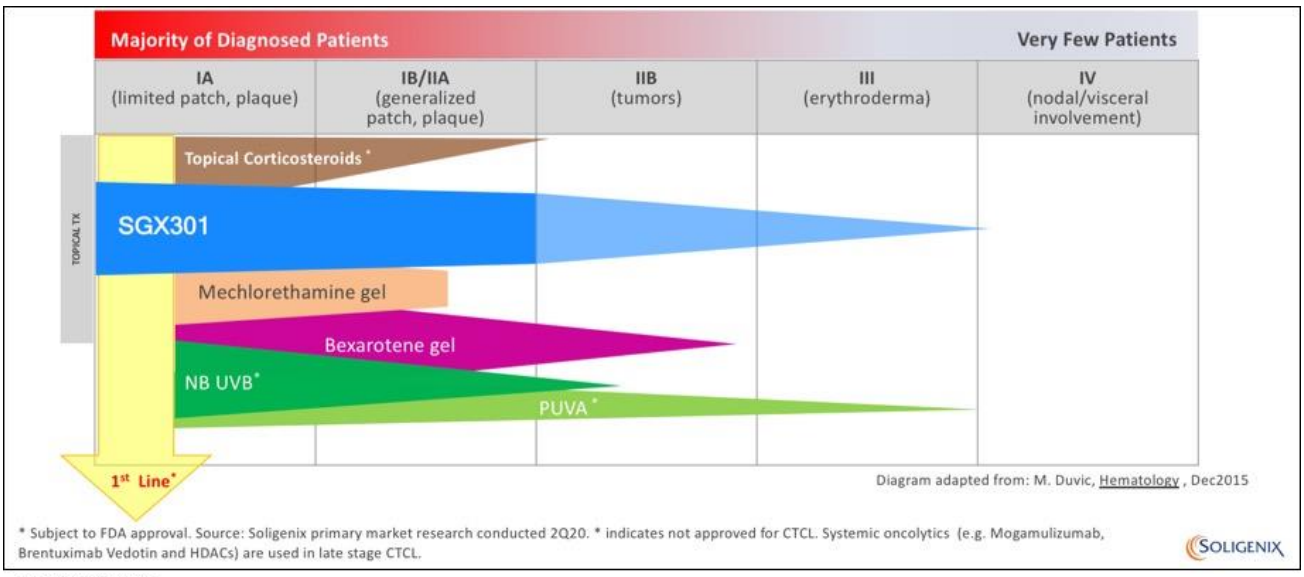
Source: Soligenix, Inc.

Background on CTCL

Dr. Ellen Kim, a lead principal investigator of the Phase 3 FLASH trial, provided an overview of CTCL. It is a rare class of non-hodgkin's lymphoma (NHL) in which malignant T cells migrate to the skin to form patches, lesions, or tumors. It affects approximately 40,000 patients worldwide (approximately 27,000 in the U.S.) and while there are treatments available, currently there is no cure.

The two main subtypes of CTCL are mycosis fungoides (MF), which is considered "early stage" disease and has a five-year overall survival of approximately 88%, and Sezary syndrome (SS), which has only a 24% 5-year overall survival rate. Fortunately, the majority of MF/SS patients early stage (IA) disease and can either choose active surveillance or skin directed therapy (85%) with the remainder being refractory and requiring additional systemic therapy.

The following chart shows some of the currently utilized CTCL therapies for early-stage patients and where SGX301 may fit into that treatment paradigm, with an explanation of the various treatment groups following.



Source: Soligenix, Inc.

Topical steroids: These are inexpensive and work quickly, however they run the risk of adverse events following long term use. In addition, they are not FDA approved for treating CTCL

Topical retinoids: These include bexarotene and tazarotene and while there are no safety issues with long-term use, there is a high incidence of irritant dermatitis along with the fact they are not fast-acting.

Topical chemotherapy: These include mechlorethamine and compounded carmustine. While these are safer than topical steroids for long term use, and are indicated as a second-line treatment for CTCL, there is a 20% incidence of allergic contact dermatitis along with taking from between 4-24 months for full response.

Topical immunotherapy: Topical imiquimod is a TLR agonist that is safe to use, even in genital areas (it has been used for treating genital warts) with a relatively quick onset of action (6-12 weeks). However, it is very expensive and can cause inflammation at application site.

Phototherapy: This includes the use of UVA, UVB, and PUVA (UVA light plus psoralen). This therapy is typically used when there is widespread skin disease, however these treatments are not FDA approved for CTCL and there is a risk for adverse skin effects, including premature aging, sunburn, and skin cancer.

Radiation therapy: This is the localized use of radiation and can be effective in a relatively quick time period. However, there is a high cost associated with the treatment and only specialized centers are able to perform the procedure. In addition, it may lead to radiation dermatitis, hair loss, and nail shedding.

Dr. Kim made the point that there is currently no one “best” therapy for CTCL patients and that few large, randomized controlled trials exist that compare treatments directly. While the initial choice depends on many factors, since CTCL is a life-long ailment with no cure a patient will typically cycle through a number of different treatments and multiple therapeutic strategies can be utilized concurrently.

A Practitioner’s Viewpoint

Dr. Brian Poligone was a lead enroller in the FLASH trial and offered his opinion on SGX301 and how it will fit into the current treatment paradigm. He began his remarks by noting that there is no cure for early-stage disease and that he prefers the use of skin-directed therapies whenever possible. With many shortcomings for the currently available skin-directed therapies, Dr. Poligone believes there is a large unmet need for a safe and effective therapy such as SGX301.

In Dr. Poligone’s experience during the FLASH trial, he noted that all of the patients he treated with SGX301 saw a benefit. In addition, he stated that the application of SGX301 was quick and intuitive and that the use of light therapy was also easy for the patients. He liked the fact that patients came into the clinic to receive light therapy as it allowed him the opportunity to examine the patients progress on a weekly basis.

His takeaways from the FLASH trial were that SGX301 is effective in treating early stage CTCL with a treatment effect that continues to increase over time. SGX301 is well tolerated, which differentiates it from essentially all other skin-directed therapies for CTCL. In his opinion, SGX301 is a viable treatment option for all of the early stage CTCL patients that he treats and he believes that its potential availability as a home treatment could be a game changer for patients.

Anticipated Milestones

The company has a number of upcoming milestones for the SGX301 program:

- The FLASH study results have been submitted for presentation at the American Academy of Dermatology Meeting in March 2021 and the Society for Investigative Dermatology Meeting in May 2021. A manuscript will likely be submitted to the peer reviewed journal *JAMA Dermatology* later in 2021.

- All patient visits have concluded for the FLASH trial and we currently anticipate final database lock and completion of the clinical study report in the second quarter of 2021. This will lead to the initial filing for

the rolling NDA in the second quarter of 2021, however this timing is contingent upon ongoing interactions with the FDA.

- As part of the life cycle management for SGX301, the company has plans to discuss with regulatory authorities what, if anything, additional is required for home use of SGX301, with an estimated timeline of approximately 12-18 months following commercial launch.

- Additional life cycle management strategies for SGX301 include expanding its use to other indications. The company previously showed statistically significant efficacy in a Phase 2 psoriasis study using a liquid formulation of hypericin. Since other photodynamic therapies used off-label in CTCL have shown efficacy in psoriasis it's not surprising that hypericin showed efficacy as well, however the company has not definitively decided what other indications may be pursued, but we anticipate an update on life cycle management strategies for hypericin as the year progresses.

- In regards to ex-U.S. markets, the company is in a number of active partnering discussions and will continue to pursue partners with similar reputation and expertise in CTCL and following approval in the U.S. pursue marketing authorizations in key ex-U.S. markets.

Conclusion

The webinar on SGX301 provided a comprehensive overview of the company's plans for commercializing SGX301, including encouraging data from primary market research with physicians and initial revenue projections. As discussed, there are a number of upcoming milestones for the company as it relates to SGX301, with perhaps the most important being the submission of the rolling NDA, which should begin in the second quarter of 2021. Based on the company's projections, we have slightly pared back our revenue forecast for SGX301, which has resulted in a slight decrease in valuation to $6.50 per share, however the stock continues to trade at a significant discount to our valuation and represents a compelling opportunity for risk-tolerant investors.

PROJECTED FINANCIALS

Soligenix, Inc.	2019 A	Q1 A	Q2 A	Q3 A	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	$0.6	$1.1	$3.1	$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**	**$0.6**	**$1.1**	**$3.1**	**$4.5**	**$25.5**
Cost of Revenue	$3.6	$0.8	$0.4	$0.4	$0.9	$2.5	$3.7	$8.0
Gross Income	**$1.1**	**$0.1**	**$0.1**	**$0.2**	**$0.2**	**$0.7**	**$0.8**	**$17.5**
Gross Margin	*22.9%*	*10.3%*	*28.1%*	*36.5%*	*18.2%*	*21.0%*	*17.8%*	*68.6%*
Research & Development	$8.1	$2.7	$2.2	$1.3	$2.5	$8.6	$10.0	$12.0
General & Administrative	$3.5	$0.9	$0.8	$0.8	$1.0	$3.4	$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)	($1.8)	($3.3)	($16.4)	($19.2)	($12.5)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.6	$0.1	$0.0	$0.0	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	**($10.0)**	**($8.4)**	**($2.8)**	**($1.8)**	**($3.3)**	**($16.2)**	**($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%*	*5.2%*	*0.0%*	*0.0%*
Reported Net Income	**($9.4)**	**($7.6)**	**($2.8)**	**($1.8)**	**($3.3)**	**($15.4)**	**($19.0)**	**($12.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.48)**	**($0.32)**	**($0.10)**	**($0.06)**	**($0.11)**	**($0.56)**	**($0.58)**	**($0.34)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	19.4	23.4	26.9	29.6	30.0	27.5	33.0	36.0

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

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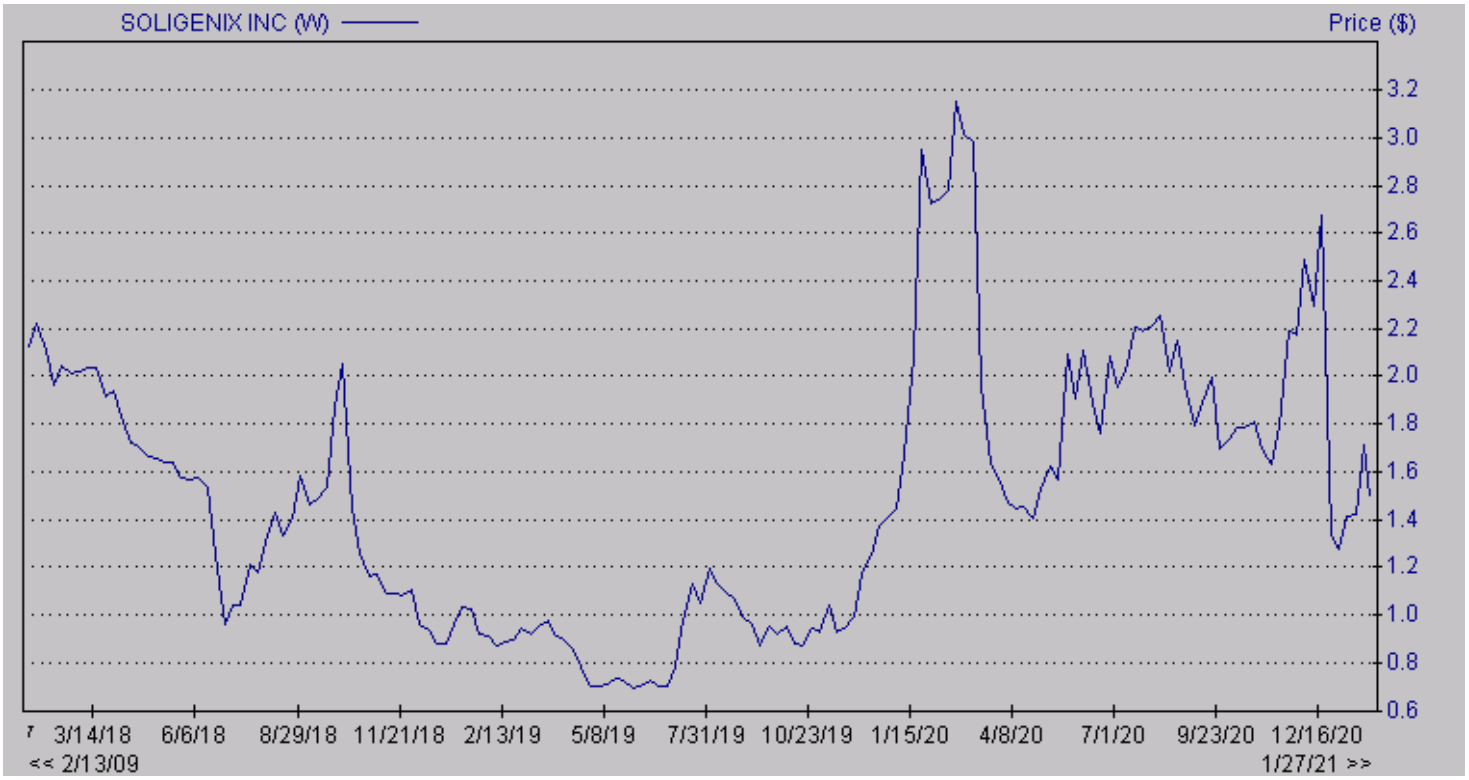

Source: Zacks Small Cap Research

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