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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Rolling NDA Submission for SGX301 to Initiate 2Q21…

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 (03/31/21)	$1.51
Valuation	**$6.50**

OUTLOOK

On March 30, 2021, Soligenix, Inc. (SNGX) announced financial results for the fourth quarter and full year 2020 and provided a business update. Following the completion of the pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, the company plans to initiate the rolling new drug application (NDA) in the second quarter of 2021. Given the limited number of CTCL treatment centers in the U.S., the company will be able to commercialize SGX301 itself with a small sales force and talks continue with potential partners regarding an ex-U.S. partnership.

In March 2021, Soligenix announced that preclinical studies of CiVax (heat stable COVID-19 vaccine program) induced a rapid, broad, neutralizing antibody and cell-mediated immune response in mice. Large animal and COVID variant studies are currently being planned.

SUMMARY DATA

52-Week High	**$2.75**
52-Week Low	**$1.26**
One-Year Return (%)	**-10.12**
Beta	**1.30**
Average Daily Volume (sh)	**3,102,168**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$48**
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	**-4.4**
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)
2020	0.9 A	0.5 A	0.6 A	0.3 A	2.4 A
2021	0.8 E	0.8 E	0.8 E	0.8 E	3.2 E
2022					14.5 E
2023					26.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.32 A	-$0.10 E	-$0.06 A	-$0.18 A	-$0.64 A
2021	-$0.11 E	-$0.13 E	-$0.16 E	-$0.18 E	-$0.59 E
2022					-$0.46 E
2023					-$0.25 E

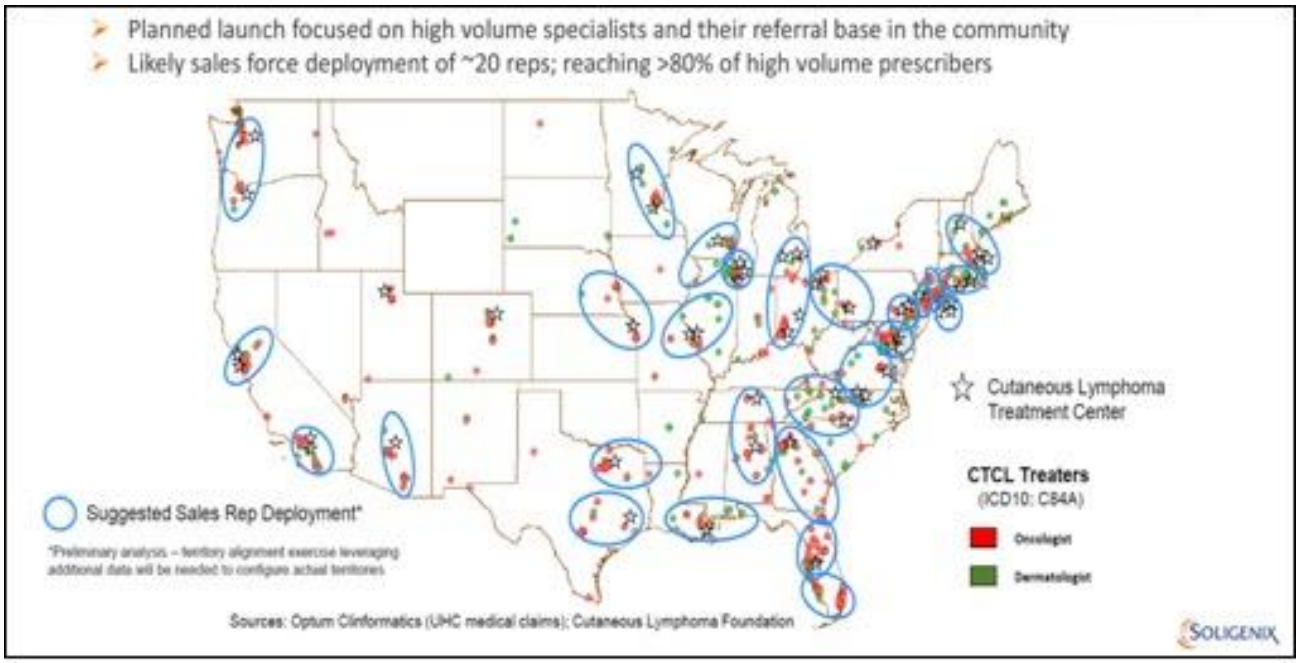
WHAT'S NEW

Business Update

Rolling NDA Submission for SGX301 to Initiate 2Q21

Soligenix, Inc. (SNGX) is developing SGX301 for the treatment of cutaneous T cell lymphoma (CTCL). The company has successfully completed the Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, which was 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). Results from the trial showed that administration of SGX301 results in a rapid treatment effect, with efficacy seen as soon as six weeks following initiation of treatment (Cycle 1; *P*=0.04), a continued improvement in patient response following 12 weeks of treatment (Cycle 2; *P*<0.0001 compared to Cycle 1), and approximately 50% of patients receiving treatment for 18 weeks reported a 50% or greater reduction in response rates (Cycle 3; *P*<0.0001 compared to Cycle 1). Based on these results, we anticipate the company initiating the submission of a rolling new drug application (NDA) in the second quarter of 2021.

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.

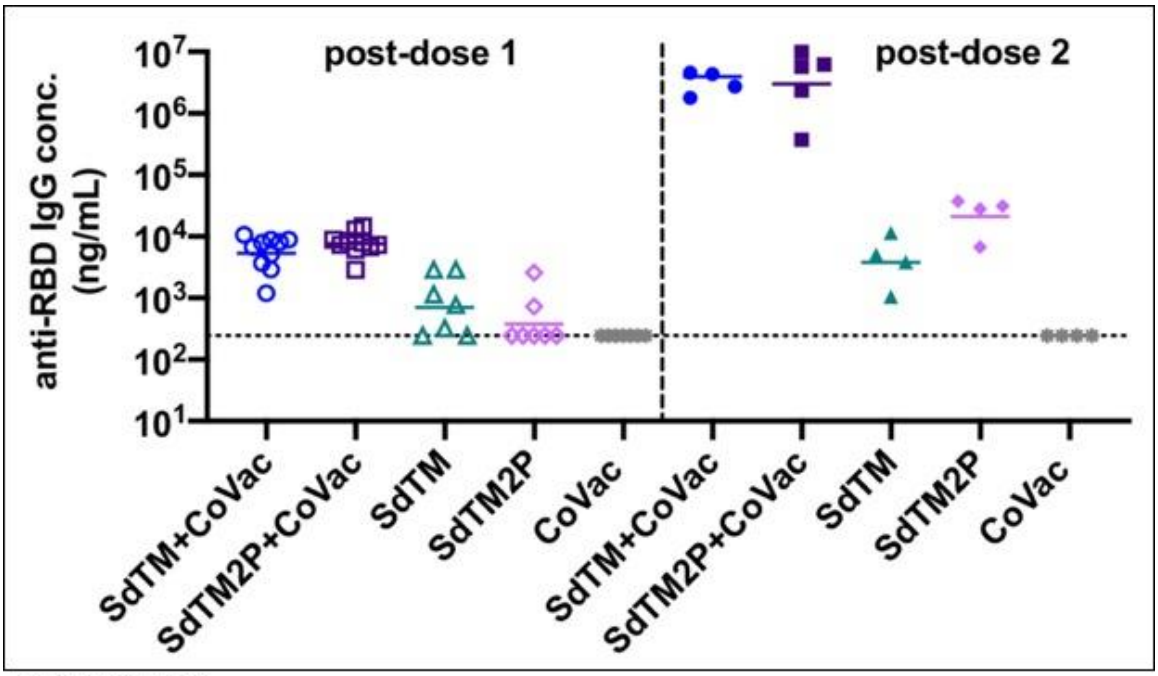
Lastly, the company announced the proposed proprietary brand name and logo for SGX301 as HyBryte™ and it has been submitted to the FDA for approval.

Source: Soligenix, Inc.

CiVax™ Induces Robust Immune Response in Mice

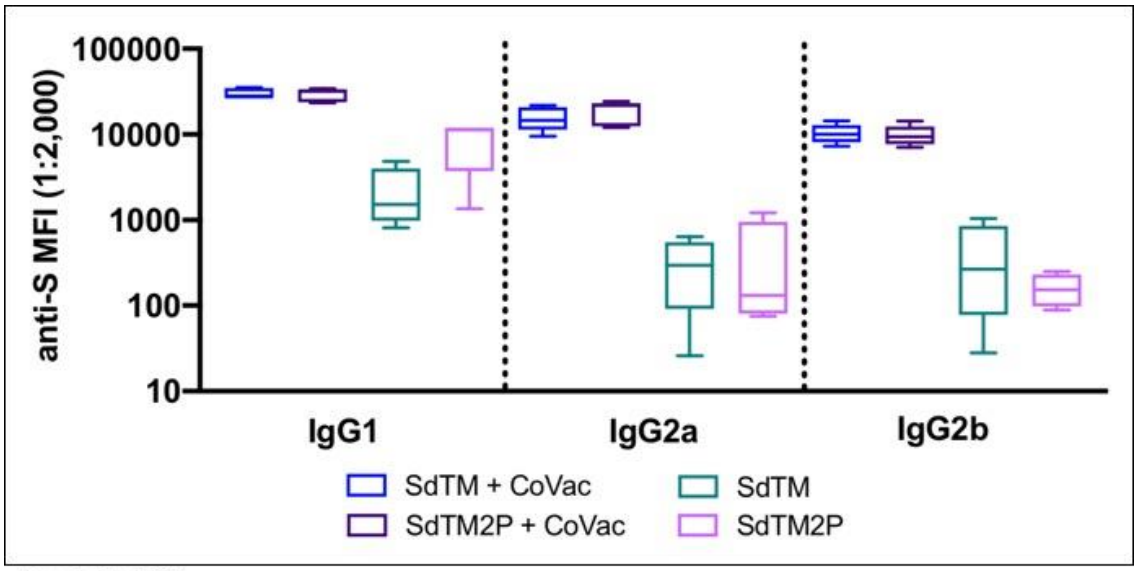
On March 4, 2021, Soligenix announced a preprint publication highlighting results from a preclinical immunogenicity study for CiVax (heat stable COVID-19 vaccine program). The article, title "Recombinant protein subunit SARS-CoV-2 vaccines formulated with CoVaccine HT adjuvant induce broad, Th1 biased, humoral and cellular immune response in mice", describes the robust immunological response induced by the full-length CiVax antigen (SARS-CoV-2 S protein) formulated with CoVaccine HT™, which can be lyophilized so as to avoid the necessity of cold chain storage (Lai *et al*., 2021).

The following figure shows that following two doses of spike (S) protein formulated with CoVaccine HT, mice develop a robust level of neutralizing antibodies targeted to the receptor binding domain (RBD) of the S protein. SdTM is the native-like, trimeric, transmembrane-deleted spike protein from SARS-CoV-2 while SdTM2P has modifications in the furin cleavage site and two proline substitutions to stabilize the prefusion structure of the S protein. Antibody levels are much higher with the addition of CoVaccine HT compared to immunization with S protein alone.



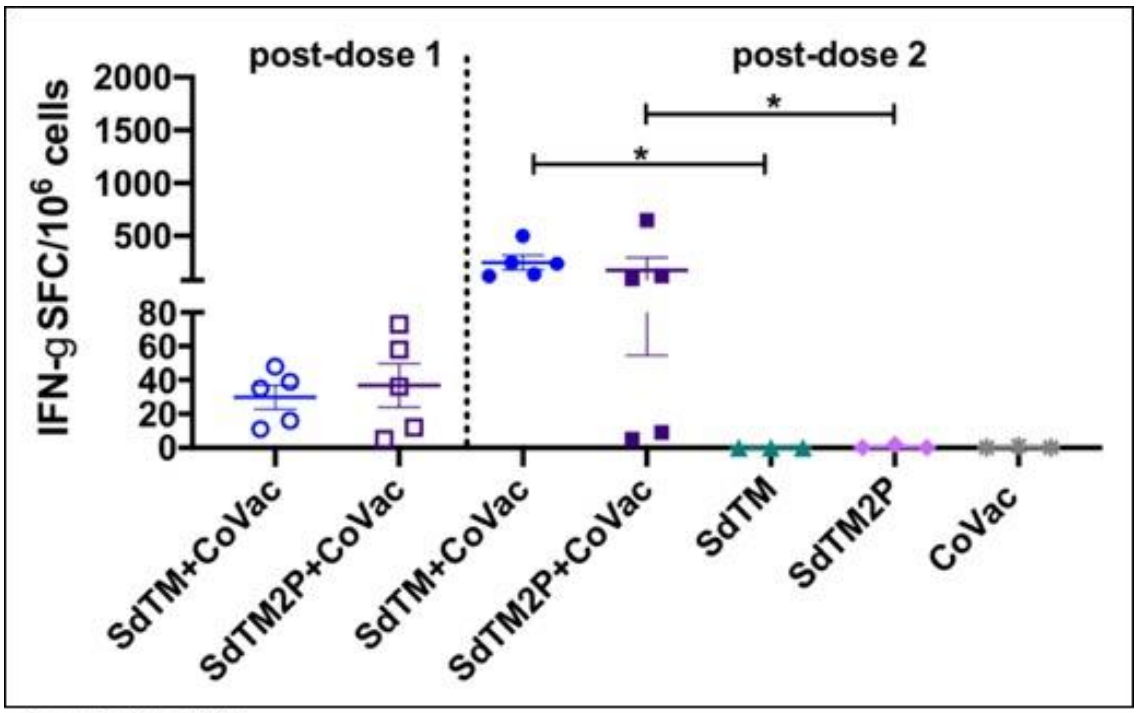
Source: Lai *et al.*, 2021

Previous attempts to develop a vaccine to SARS-CoV resulted in a pulmonary immunopathology that is associated with a Th2-biased immune response (Bolles *et al*., 2011; Tseng *et al*., 2012). To determine the type of immune response generated by CiVax the levels of S-specific IgG2a/b and IgG1, which are indicative of a Th1 and Th2 response, respectively, were evaluated. The following figure shows that both SdTM and SdTM2P adjuvanted with CoVaccine HT elicit high anti-S IgG2a/b and IgG1 antibodies. When the proteins are immunized alone the response is more biased to a Th2 response, as shown by the higher IgG1 levels compared to IgG2a/b.



Source: Lai *et al*., 2021

To examine T cell responses following immunization with S protein, the number of interferon-gamma (IFN-g) secreting cells was examined by FluoroSpot assay. Cells were prepared from mice receiving two doses of SdTM or SdTM2P with and without CoVaccine HT. A robust number of IFN-g secreting cells was elicited following immunization with either SdTM or SdTM2P with CoVaccine HT. No T cell response was seen in animals immunized with protein alone.



Source: Lai *et al*., 2021

Financial Update

On March 30, 2021, Soligenix announced financial results for 2020. The company reported revenues of $2.4 million for 2020, compared to $4.6 million for 2019. The revenues include payments on a contract to support the development of RiVax® along with grants received to support the development of SGX943, ThermoVax®, and the assessment of SGX942 safety in juvenile animals. R&D expenses were $10.1 million in 2019, compared to $8.1 million for 2019. The increase was primiarly due to the expansion of the Phase 3 clinical trial of SGX942 along with the ongoing Phase 3 trial of SGX301. G&A expenses in 2020 were $4.0 million, compared to $3.5 million in 2019.

Soligenix currently has more than $30 million in cash and cash equivalents. In December 2020, the company entered into a $20 million convertible debt financing agreement with Pontifax Medison Debt Financing. Upon closing of the transaction, Soligenix accessed the first tranche of $10 million, with the option to draw the second tranche of $5 million at any time over the next 12 months and the third tranche of $5 million upon filing the SGX301 NDA. Pontifax may elect to convert the outstanding loan drawn under the first two tranches into shares of Soligenix common stock at a conversion price of $4.10 per share, while Soligenix has the ability to force the conversion of the loan into shares of common stock at a conversion price of $4.92 per share.

As of March 30, 2021, Soligenix had approximately 40 million shares outstanding, and when factoring in stock options, warrants, and the potential convertible debt the fully diluted share count is approximately 50 million.

Conclusion

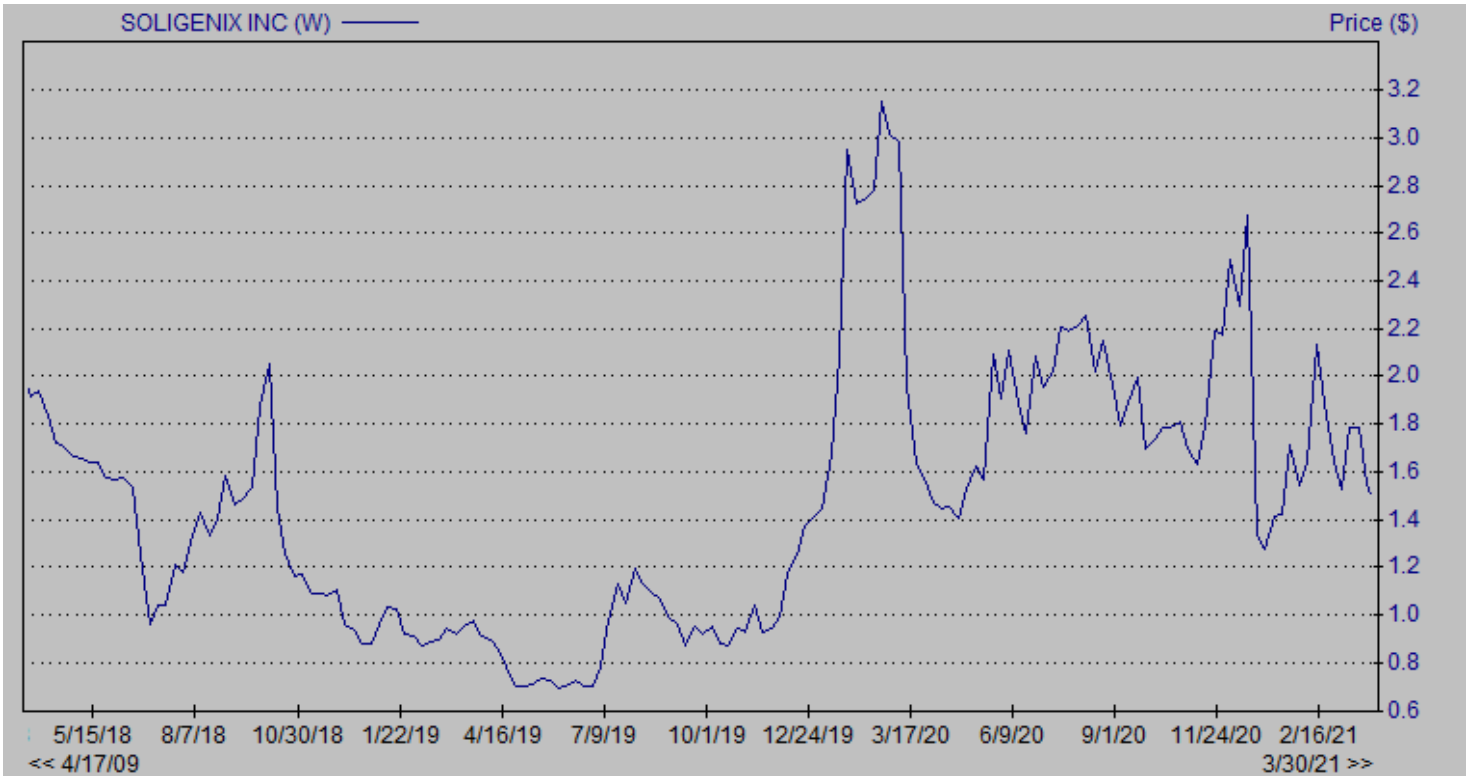
Soligenix is poised to begin the rolling NDA submission for SGX301 and we look forward to updates from the company as that process unfolds this year. The U.S. CTCL market represents a potential $90 million opportunity for the company and can be accessed using a small, focused sales team. The international market is a potential $250 million opportunity and we look forward to updates this year regarding partnering discussions. Even with multiple COVID-19 vaccines being deployed under emergency use authorizations (EUA), the need still exists for an effective vaccine that does not require cold chain storage, particularly for resource-poor countries, and the data announced thus far for CiVax is highly encouraging. With no changes to our model the valuation remains at $6.50.

PROJECTED FINANCIALS

Soligenix, Inc.	2020 A	Q1 E	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$2.4	$0.8	$0.8	$0.8	$0.8	$3.2	$4.5	$4.5
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$10.0	$22.0
Public Health Solutions	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$2.4**	**$0.8**	**$0.8**	**$0.8**	**$0.8**	**$3.2**	**$14.5**	**$26.5**
Cost of Revenue	$1.8	$0.6	$0.6	$0.6	$0.6	$2.4	$5.4	$6.5
Gross Income	**$0.5**	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$0.8**	**$9.1**	**$20.0**
Gross Margin	*22.8%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*62.8%*	*75.5%*
Research & Development	$10.1	$3.0	$3.5	$4.0	$4.5	$15.0	$16.0	$17.0
General & Administrative	$4.0	$0.9	$2.0	$2.8	$3.5	$9.2	$15.0	$16.0
Other Expenses	$5.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($18.6)	($3.7)	($5.3)	($6.6)	($7.8)	($23.4)	($21.9)	($13.0)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.1	$0.2	$0.2	$0.2	$0.2	$0.9	$0.9	$0.8
Pre-Tax Income	**($18.5)**	**($3.9)**	**($5.5)**	**($6.8)**	**($8.0)**	**($24.2)**	**($22.8)**	**($13.8)**
Net Taxes (benefit)	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*4.5%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($17.7)**	**($3.9)**	**($5.5)**	**($6.8)**	**($8.0)**	**($24.2)**	**($22.8)**	**($13.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.64)**	**($0.11)**	**($0.13)**	**($0.16)**	**($0.18)**	**($0.59)**	**($0.46)**	**($0.25)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	27.5	35.0	41.0	43.0	45.0	41.0	50.0	55.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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