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Soligenix, Inc. (SNGX-NASDAQ)

SNGX: Interim Analysis of SGX942 in Oral Mucositis in Third Quarter of 2019…

Based on our probability adjusted DCF model that takes into account potential future revenues from SGX301 and SGX942, SNGX is valued at $8.50 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 (03/29/19)	$0.89
Valuation	**$8.50**

OUTLOOK

On March 26, 2019, Soligenix, Inc. (SNGX) announced financial results for 2018 and provided a business update. The company is currently conducting two Phase 3 clinical trials for its lead development programs SGX942 (dusquetide) and SGX301. SGX942 (dusquetide) is an innate defense regulator being tested in patients with oral mucositis, with interim results expected in the third quarter of 2019. SGX301 is a photodynamic therapy that is being tested in patients with cutaneous T-cell lymphoma. We anticipate topline results in the first quarter of 2020.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.85**
One-Year Return (%)	**-54.38**
Beta	**1.33**
Average Daily Volume (sh)	**74,366**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$15**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**15.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-2.2**
P/E using 2019 Estimate	**-2.5**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	1.1 A	1.7 A	1.4 A	1.0 A	5.2 A
2019	1.3 E	1.4 E	1.4 E	1.5 E	5.6 E
2020					5.8 E
2021					6.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.27 A	-$0.18 A	-$0.11 A	-$0.17 A	-$0.67 A
2018	-$0.13 A	-$0.13 A	-$0.14 A	-$0.14 E	-$0.53 E
2019					-$0.48 E
2020					-$0.48 E

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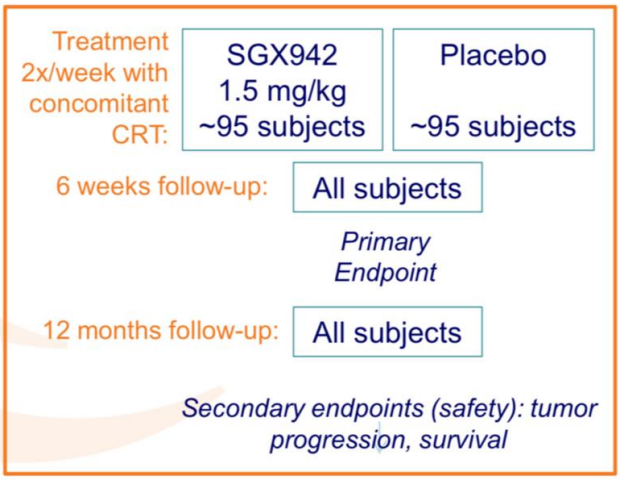
WHAT'S NEW

Business Update

Interim Analysis in Phase 3 Trial of SGX942 in 3Q19

Soligenix, Inc. (SNGX) is currently conducting the randomized, multinational, double blind, placebo controlled Phase 3 DOM-INNATE (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity) clinical trial, which is evaluating SGX942 (dusquetide) for the treatment of severe oral mucositis (OM) in patients with squamous cell carcinoma of the oral cavity and oropharynx undergoing chemoradiation therapy. The trial is being supported in part by a $1.5 million SBIR grant awarded by the National Institute of Dental and Craniofacial Research (NIDCR), a part of the NIH. In September 2018, Soligenix announced that it was selected by the NIH as an SBIR Commercialization Accelerator Program (CAP) Phase II awardee. As part of the award, the SGX942 program was selected for the Commercialization Transition Track, which provides assistance to awardees of NIH-funded technologies to get products to market. In addition, SGX942 has received both Fast Track designation from the FDA as well as Promising Innovative Medicine designation from the UK MHRA.

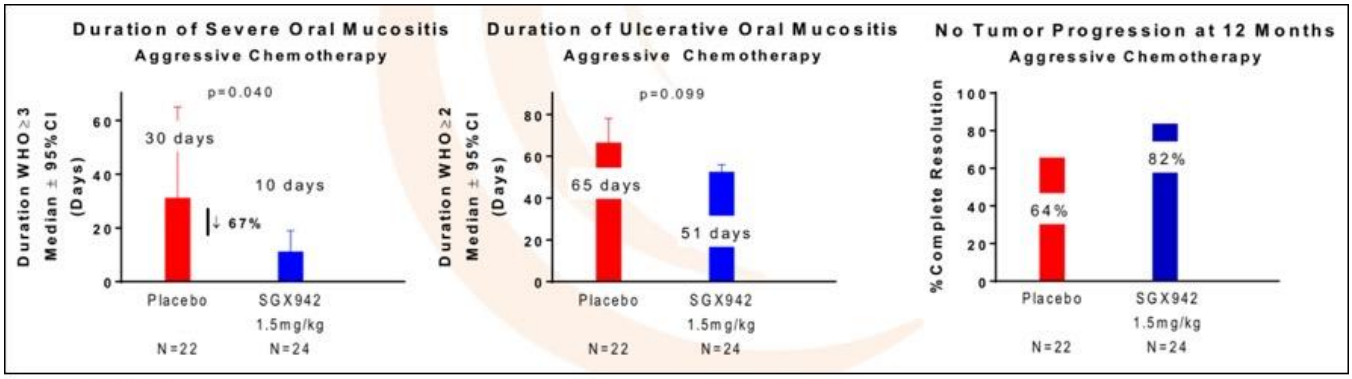
We anticipate approximately 190 patients will be randomized to receive twice weekly injections of either 1.5 mg/kg SGX942 or placebo. Dosing will be given during chemoradiation treatment and then for two weeks following its completion. The primary endpoint of the study is the median duration of severe OM using the World Health Organization (WHO) Oral Toxicity Scale (discussed below), which will be assessed at each treatment visit and then through six weeks following completion of chemoradiation treatment. Important secondary endpoints that are being evaluated include tumor progression and overall survival at 12 months. We anticipate an interim analysis taking place in the third quarter of 2019 with topline results being available in the first half of 2020. An outline of the trial protocol is shown below.



Source: Soligenix, Inc.

Encouraging Phase 2 Data for SGX942

Soligenix had previously completed a proof-of-concept Phase 2 study of SGX942 in 111 head and neck cancer patients in 2015 (Kudrimoti *et al*., 2016). Results showed that administration of 1.5 mg/kg SGX942 reduced the median duration of severe OM by 67% (30 days vs.10 days for the placebo and SGX942 groups, respectively) in those patients receiving the most aggressive form of chemoradiation therapy (below left). In addition, there was a decrease in the median duration of ulcerative OM, which met the pre-specified threshold for significance of $P<0.1$ (below middle). Lastly, treatment with SGX942 appeared to increase the efficacy of treatment, as a greater percentage of those treated with SGX942 saw complete resolution at the 12-month mark than those treated with placebo (below right).



Source: Soligenix, Inc.

SGX942 was found to be generally safe and well tolerated, which is consistent with safety results observed in a Phase 1 study of the drug in healthy volunteers. Additional findings from the Phase 2 study included the fact that those administered 1.5 mg/kg SGX942 had a 40% decrease in the use of opioids for pain management during the later stage of the chemoradiation treatment when OM is most likely to be its most severe. This was in contrast to those administered placebo that had a 10% increase in opioid usage during that same time period.

Oral Mucositis

Mucositis is a common and debilitating side effect of cancer chemotherapy and radiation treatment. It results in damage to the epithelial cells that line the gastrointestinal tract and can present as sores and ulcers in the mouth and throat (oral mucositis, OM) or abdominal pain, nausea/vomiting, and diarrhea (gastrointestinal mucositis). OM occurs in approximately 40% of patients receiving chemotherapy treatment, although harsher chemotherapies (e.g., cisplatin, doxorubicin, 5-fluorouracil, etc.) carry a greater risk (Jones *et al.*, 2006). The following image shows a patient with severe OM.



Source: myhealth.gov.my

OM is typically graded according to two scales: WHO Oral Toxicity Scale and the National Cancer Institute's (NCI) Common Toxicity Scale, which are shown below. These tools are composed of four or five-point scales that rate the overall health of the mouth, the severity of patient pain, and the patient's functional capability.

WHO Grading Scale for OM

Grade	Description
0 (none)	None
1 (mild)	Oral soreness, erythema
2 (moderate)	Oral erythema, ulcers, solid diet tolerated
3 (severe)	Oral ulcers, liquid diet only
4 (life-threatening)	Oral alimentation impossible

Source: WHO

NCI Grading Scale for OM

Grade	Description
0 (none)	None
1 (mild)	Painless ulcers, erythema, or mild soreness
2 (moderate)	Painful erythema, edema, or ulcers
3 (severe)	Painful erythema, edema, or ulcers requiring IV hydration
4 (life-threatening)	Severe ulceration requiring nutrional support
5 (death)	Death related to toxicity

Source: Sonis et al., 2004

In addition to degrading a patient's quality of life, severe OM can result in a reduction in a patient's chemotherapy dose or a stoppage in treatment, both of which can lead to a negative clinical outcome, or an increase in infection (Elting *et al*., 2003). There are also serious economic consequences due to the costs associated with symptom management, nutritional support, managing infections, and increased hospital stays. Thus, OM constitutes a serious complication of chemotherapy and radiation treatment.

Treatment of OM

The first evidence-based clinical practice guidelines that discussed care of mucositis were published in 2004 by the Mucositis Study Group of the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) and updated in 2014 (Lalla *et al*., 2014). Treatments are divided into the following categories:

Basic oral care: This consists of debridement and decontamination. Debridement is usually done with a soft-bristle toothbrush to remove the dead tissue. Antifungal and antibacterial mouthwashes are used to prevent infection, however none of those treatments have been shown to reduce the risk of developing OM.

Topical and systemic pain management: Mouth rinses containing lidocaine or morphine along with systemic analgesics are used to control pain. Gelclair® is an FDA approved oral gel that forms a protective film over lesions in the mouth of those suffering from OM. Caphasol® is an FDA approved mouth rinse designed to moisten and lubricate the oral cavity. MuGuard® is an oral wound rinse that forms a protective layer on the mucosal membranes in the mouth.

Prophylaxis: Sucking on ice during administration of bolus 5-fluorouracil or melphalan has been shown to decrease the severity of OM. This is believed to work through vasoconstriction that reduces blood flow to cells in the mouth and limits exposure of those cells to the chemotherapeutic agent.

Kepivance® (palifermin) is a recombinant keratinocyte growth factor that is administered intravenously to decrease the incidence and duration of severe OM for patients receiving myelotoxic therapy prior to autologous hematopoietic stem cell transplant. A study from the early 2000's showed that administration of palifermin for three consecutive days prior to the initiation of conditioning therapy and three consecutive days following transplantation resulted in a statistically significant decrease in the incidence and duration of severe OM (Spielberger *et al*., 2004). The incidence of severe OM (WHO grade 3 or 4) in the palifermin-treated group was 63% compared to 98% in the placebo group (P<0.001). In addition, the median duration of severe OM in the palifermin-treated group was three days compared to nine days in the placebo group (P<0.001). Treatment of patients with solid tumors with palifermin is contra-indicated due to the risk palifermin will support cancer tumor growth.

While there are some palliative treatments available to reduce the effects of OM, there does not currently exist an FDA approved therapy for the prevention of OM in a large cancer population. With so many patients affected by the condition, there is clearly a pressing need for more effective treatment and preventative options for OM that target its underlying pathology.

SGX942 (Dusquetide)

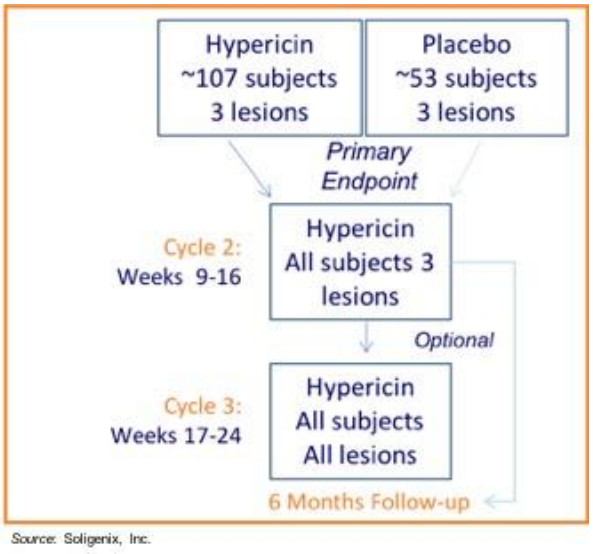
SGX942 belongs to a new class of compounds known as innate defense regulators (IDRs). It is a five amino acid peptide that binds to the intracellular protein sequestosome-1 (p62), which acts as a signal transducer during activation and control of the innate immune system. This novel mechanism of action leads to a number of observed activities for SGX942, including anti-inflammatory and anti-infective properties. While IDRs have no direct antibiotic activity, preclinical studies show that they modulate the immune response and ultimately lead to an increase in survival against many different types of Gram-positive and Gram-negative pathogens. For a full overview of IDRs, please see our previous report.

Phase 3 Clinical Trial of SGX301 Continues

Soligenix is currently conducting the Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, which is testing SGX301 in patients with cutaneous T cell lymphoma (CTCL). In October 2018, the company announced a positive recommendation from the independent Data Monitoring Committee (DMC), which recommended that the company enroll an additional 40 subjects into the trial to maintain 90% statistical power for the primary endpoint. Please see our previous Q&A session with Soligenix's Chief Medical Officer that provides additional details about the interim analysis and the recommendations from the DMC.

SGX301, the active ingredient of which is synthetic hypericin, is a photodynamic therapy that is activated by visible light. Hypericin is topically applied to lesions on the skin, where it is taken up by malignant cells at a much higher rate than normal, healthy cells. Approximately 16-24 hours later the treated area is exposed to visible fluorescent light. Exposure of hypericin to light results in the production of singlet oxygen (Thomas *et al*., 1992), which is a highly reactive species that ultimately leads to the initiation of apoptosis in the cell.

The FLASH trial is a randomized, double blind, placebo controlled study that was originally expected to enroll approximately 120 subjects with either Stage IA, IB, or IIA mycosis fungoides (the most common type of CTCL) across 30 centers in the U.S. Following the recommendation by the DMC, we now anticipate total enrollment to be approximately 160 subjects. The trial consists of three treatment cycles, with each cycle lasting eight weeks. Each study subject will have three target lesions treated during the trial. In cycle one, patients will be randomized 2:1 to receive twice weekly treatment of other 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 two, all subjects will receive SGX301 on their target lesions, and for those that decide to continue in the trial there is a third treatment cycle where SGX301 will be applied to all of the patient's lesions. Thus far, the majority of patients who have made it to the third cycle of the trial have elected to continue with it. The primary endpoint of the trial is the percentage of patients achieving a partial or complete response of the treated lesions, which is defined as a ≥50% reduction in the total Composite Assessment of Index Lesion Disease Severity (CAILS) score at the end of cycle 1 (week 8) compared to the CAILS score at baseline. Secondary endpoints include duration of treatment response, degree of lesion improvement, and safety. An outline of the trial is shown below.



The interim analysis was performed using data from approximately 100 subjects, and we anticipate the trial being completed by the end of 2019 and topline data being reported no later than the first quarter of 2020.

Phase 2 Study Showed SGX301 to be Safe and Efficacious

A multicenter, open label, placebo controlled phase 2 study of SGX301 was previously conducted to test its safety and efficacy in patients with mycosis fungoides (MF) or plaque psoriasis (PS) (Rook *et al*., 2010). A total of 25 patients were enrolled (n=12 in MF arm; n=13 in PS arm) with 24 evaluable. Hypericin was administered in concentrations of 0.05%, 0.1%, or 0.25% twice weekly followed 24 hours later by visible fluorescent light treatment. The following table shows the results for the MF patients, with 7/12 (58.3%) of all hypericin-treated patients being responders.

Treatment group	Responders/total*	Percent responders*
All hypericin responders	7/12	58.3%†
Hypericin 0.25% dose	5/9‡	55.6%†
Hypericin 0.1% dose	5/12	41.7%†
Hypericin 0.05% dose	1/2	50.0%
Placebo responders	1/12	8.3%

Source: Rook et al., 2010

Importantly, there were no serious adverse events reported during the study. The most common adverse events reported were mild to moderate and included burning, itching, erythema, and pruritis.

Vaccine/BioDefense Programs Update

In addition to the company's two Phase 3 assets described above, Soligenix is also developing vaccine and biodefense products using non-dilutive funds obtained from government grants and contracts.

ThermoVax®: This is the company's proprietary stabilizing technology that allows aluminum salt (Alum) adjuvanted vaccines to be kept out of cold storage without affecting the efficacy of the product. Most Alum adjuvanted vaccines require cold temperature storage (4°C), which can be quite burdensome and costly. Elimination of the need for cold storage could significantly expand the use of certain vaccines and allow for ease of storage for strategic national stockpile vaccines.

The utility of ThermoVax® was shown through the protection of the company's ricin toxin vaccine (RiVax®, discussed below), where formulations of the vaccine produced with and without ThermoVax® were stored at 40°C for one year. The ThermoVax® formulated vaccine led to the production of potent, neutralizing antibody titers while animals immunized with the vaccine produced without ThermoVax® did not develop neutralizing antibodies and were susceptible to ricin exposure. A similar study was conducted with the company's anthrax vaccine candidate (VeloThrax®) and a human papillomavirus (HPV) vaccine. Most recently, an article was published showing the ability of ThermoVax® to maintin potency of an experimental Ebola vaccine even when stored at 40°C for 12 weeks (Chisholm *et al*., 2019). The Ebola research is being supported by a NIAID research project grant awarded to the University of Hawaii Manoa.

RiVax®: This 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. 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). In November 2018, the company presented RiVax® data at the Fourth International Conference on Vaccines Research and Development Development and discussed its development under the Animal Rule. 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 $24.7 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 between $80-$100 million each.

The company recently announced additional IP protection for RiVax® as the USPTO allowed a new US Patent titled "Multivalent Stable Vaccine Composition and Methods of making same", with claims supporting combination vaccines protective against ricin toxin and other toxins, including anthrax.

Financial Update

On March 26, 2019, Soligenix announced financial results for 2018. The company reported revenues in 2018 of $5.2 million, compared to $5.4 million for 2017. The company revenues are primarily the result of government grants and contracts. The decrease in revenues in 2018 compared to 2017 is primarily due to the completion of the NIAID contract for OrbeShield® during the first quarter of 2017 and the expiration of the BARDA contract for OrbeShield®. Costs related to contract and grant revenues were $4.6 million and $4.3 million in 2018 and 2017, respectively. The increase was the result of increased expenditures necessary to support the development of RiVax® along with reimbursable costs on the Phase 3 trials of SGX301 and SGX942.

Net loss for 2018 was $8.9 million, or $0.67 per share, compared to a net loss of $7.1 million, or $1.16 per share, in 2017. R&D expenses were $6.8 million in 2018 compared to $5.5 million in 2017. The increase was primarily due to increased expeditures for the Phase 3 clinical trials of SGX942 and SGX301. G&A expenses were $3.0 million in 2018 compared to $3.2 million in 2017. The decrease was primarily due to a decrease in professional fees and employee compensation expenses.

As of December 31, 2018, Soligenix had cash and cash equivalents of $9.0 million. The company had approximately 17.7 million shares of common stock outstanding as of December 31, 2018 and when factoring in options and warrants a fully diluted share count of 25.0 million.

Conclusion

We value Soligenix using a probability adjusted discounted cash flow analysis based on potential future revenues of SGX301 in CTCL and SGX942 in OM. For SGX301, we model for approval in 2021 and peak revenues of approximately $200 million worldwide. Using a 70% probability of approval and a 13% discount rate leads to a net present value of $73 million. For SGX942, we model for approval in 2021 and peak revenues of approximately $350 million worldwide. Using a 60% probability of approval and a 13% discount rate leads to a net present value of $104 million. Combining the net present value for those two products with the company's current cash position, the potential cash from exercising warrants, and using a fully diluted share count of 25.0 million shares leads to a valuation of approximately $8.50 per share. Soligenix is currently trading at a significant discount to our valuation, and with two Phase 3 readouts due by the first half of 2020 we believe investors would be well served to take a closer look at the company in the leadup to those readouts.

PROJECTED FINANCIALS

Soligenix, Inc.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant/Contract Revenue	$5.2	$1.3	$1.4	$1.4	$1.5	$5.6	$5.8	$6.0
SGX301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SGX942	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.2**	**$1.3**	**$1.4**	**$1.4**	**$1.5**	**$5.6**	**$5.8**	**$6.0**
Cost of Revenue	$4.6	$1.0	$1.2	$1.2	$1.3	$4.7	$4.9	$5.1
Gross Income	**$0.6**	**$0.3**	**$0.2**	**$0.2**	**$0.2**	**$0.9**	**$0.9**	**$1.0**
Gross Margin	*12.3%*	*24.7%*	*14.3%*	*13.1%*	*13.3%*	*16.2%*	*15.5%*	*15.8%*
Research & Development	$6.8	$1.8	$1.8	$1.9	$1.9	$7.4	$8.2	$9.8
General & Administrative	$3.0	$0.8	$0.8	$0.8	$0.8	$3.2	$3.7	$4.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($9.1)**	**($2.3)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.7)**	**($11.0)**	**($12.9)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.2	$0.1	$0.1	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	**($8.9)**	**($2.2)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.5)**	**($11.0)**	**($12.9)**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($8.9)**	**($2.2)**	**($2.4)**	**($2.5)**	**($2.5)**	**($9.5)**	**($11.0)**	**($12.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.13)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.53)**	**($0.48)**	**($0.48)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.2	17.7	17.9	18.0	18.1	17.9	23.0	27.0

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

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