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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

FibroBiologics, Inc. (FBLG-NASDAQ)

FBLG: Analyst Day Provides In-Depth Overview of Pipeline…

Based on our probability adjusted DCF model that takes into account potential future revenues of CybroCell, CYMS101, CYWC628, and psoriasis treatment FBLG is valued at $11.00 per share. This model is highly dependent upon the continued clinical success of the company's development candidates and will be adjusted accordingly based upon future clinical results.

Current Price (02/24/25)	$1.13
Valuation	**$11.00**

OUTLOOK

On February 12, 2025, FibroBiologics, Inc. (FBLG) held an Analyst Day and provided an in-depth overview of the company's technology and pipeline. The company discussed a wealth of pre-clinical data showing the potential for its fibroblast-based therapies. Right now, the company is focused on developing treatments for diabetic foot ulcers (DFUs), autoimmune diseases (multiple sclerosis and psoriasis), and has early-stage products investigating the potential for an artificial thymus organoid and cancer therapies. The company will be initiating a Phase 1/2 trial of CYWC628 for the treatment of diabetic foot ulcers in the second quarter of 2025 and should complete IND-enabling work for a psoriasis treatment by the end of 2025.

SUMMARY DATA

52-Week High	**$13.06**
52-Week Low	**$1.11**
One-Year Return (%)	**-90.72**
Beta	**N/A**
Average Daily Volume (sh)	**518,115**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$41**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**21**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2024	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share

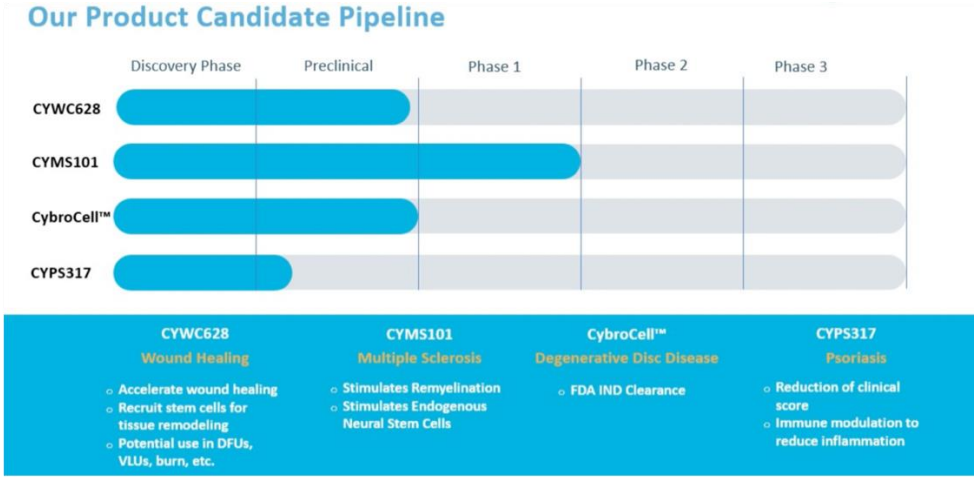
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.17 A	-$0.17 A	-$0.17 A	-$0.17 A	-$0.68 A
2024	-$0.27 A	$0.03 A	-$0.01 A	-$0.09 E	-$0.33 E
2025					-$0.29 E
2026					$0.29 E

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WHAT'S NEW

Business Update

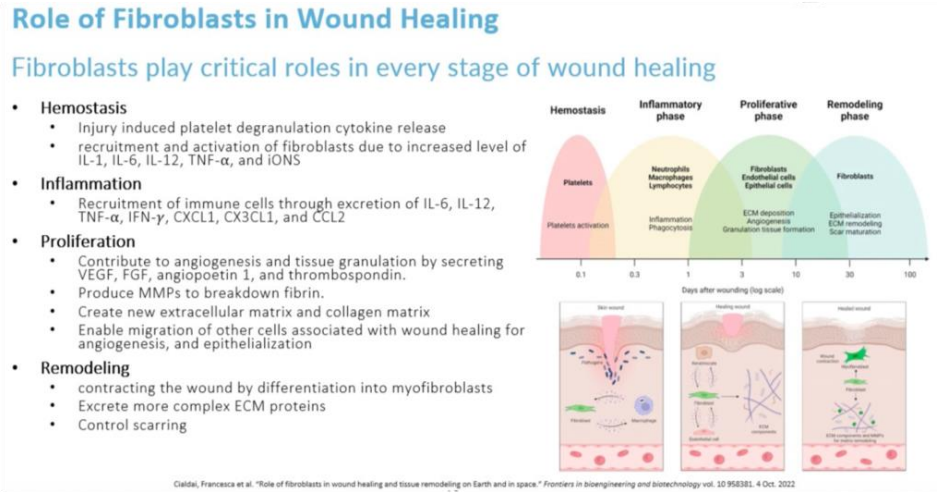
On February 12, 2025, Fibrobiologics, Inc. (FBLG) held an Analyst Day and provided a comprehensive update on the company and its fibroblast-based development products. The presentation can be viewed here. The company is currently focused on a number of different therapeutic areas, including diabetic foot ulcers, multiple sclerosis, and psoriasis along with early-stage research in thymus regeneration, cancer, and pancreatic organoid.



Source: FibroBiologics, Inc.

CYWC628: This is being developed for the treatment of diabetic foot ulcers (DFUs), which cause significant morbidity for the 6.3% of diabetic adults (~33 million) that develop them. Of those, 20% will require lower extremity amputation and 10% will die within the first year of their first DFU. In addition, once a DFU forms there is a high rate of recurrence, both at one year (40%) and three years (70%).

Fibroblasts have excellent therapeutic potential in the treatment of DFUs due to the critical role they play in every stage of wound healing, including hemostasis, inflammation, proliferation, and remodeling. Importantly, fibroblasts are the key cells that secrete extracellular matrix proteins that maintain all the tissues and organs in the body.

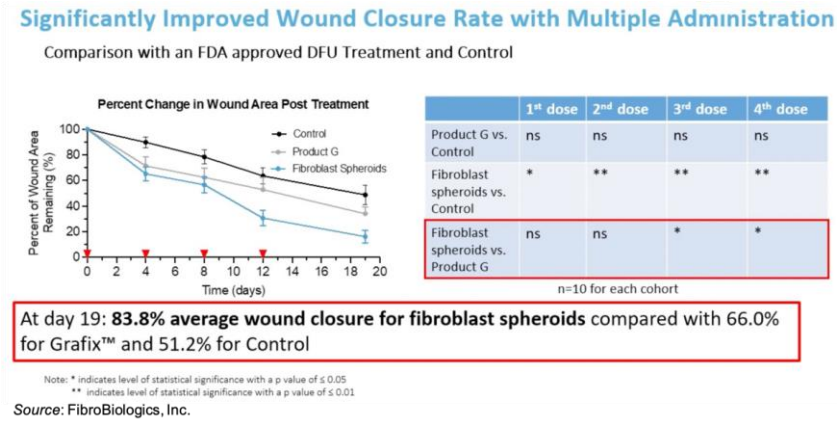


Source: FibroBiologics, Inc.

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The company does not utilize single cell fibroblasts for treatment but instead a fibroblast spheroid, which is composed of approximately 3,000 fibroblasts and is administered to the top of the wound at which time the cells migrate from the surface of the wound and release various cytokines and growth factors to initiate the wound healing process. The use of spheroids is more practical from a therapeutic perspective as they have higher viability than single cells, they don't require pre-culturing before administration, they can be easily frozen and thawed, and they have a significantly higher potency and efficacy compared to single cells.

FibroBiologics has compiled a robust pre-clinical data set showing the efficacy of fibroblast spheroids in the treatment of wounds. For example, the following figure shows results using a diabetic mouse model in which administration of fibroblasts led to a statistically significant average 83.8% wound closure by Day 19 compared to 66.0% for Grafix™ and only 51.2% for control.



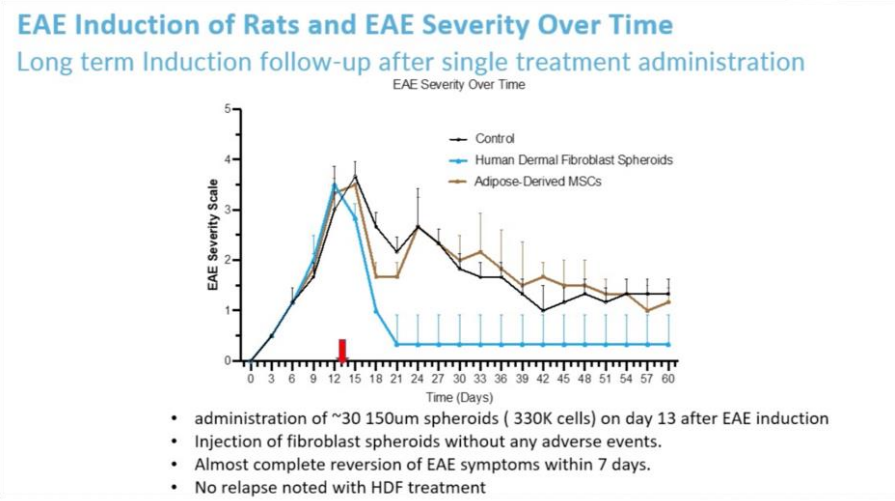
While wound healing is important, the quality of the wound healing is just as important. FibroBiologics has data on seven key biomarkers that are key to demonstrating the quality of the wound healing. Fibroblast treatment shows much better re-epithelialization, granulation, cell proliferation, neo-vascularization, recruitment and proliferation of fibroblasts, keratinocyte migration, and epithelial-mesenchymal transition. Intriguingly, even though the fibroblast spheroids are administered topically, there appears to be a systemic effect on cytokine levels, including IL-6, TNF-α, IL-1β, and IL-10.

The use of fibroblast spheroids for wound healing can be thought of as a platform technology. In addition to the treatment of DFUs, fibroblast spheroids could also be used for the treatment of burns and surgical wounds.

In regards to safety, the company has performed a number of experiments to examine any potential adverse events associated with fibroblast-based therapy. The cells do not graft into tissue. Following application, the cells stay on the surface of the wound and initiate the healing process before gradually dying off within four days of treatment. In addition, there is no impact on CBC, WBC, liver function, or kidney function, thus showing that administration of fibroblasts appears to be quite safe.

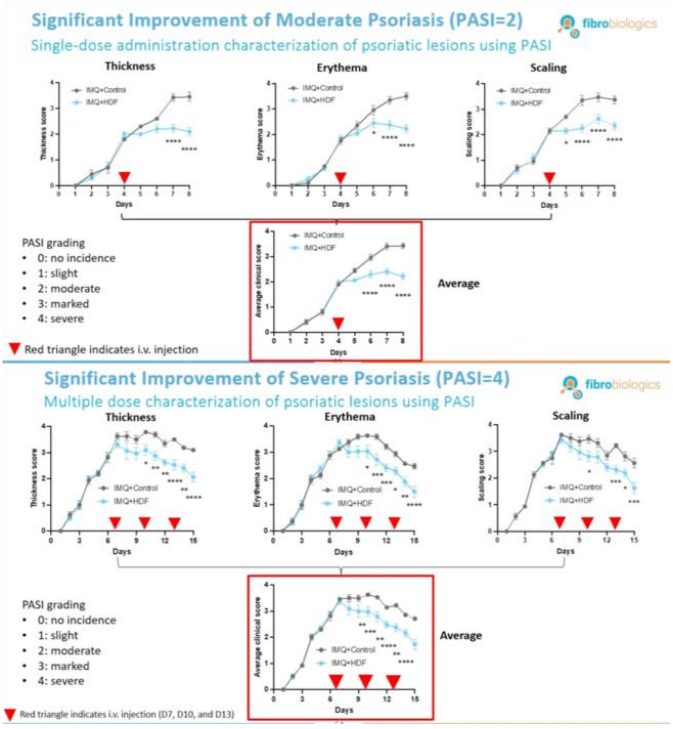
CYMS101 and CYPS317: Both of these products are being developed as therapies for autoimmune disorders; CYMS101 for multiple sclerosis (MS) and CYPS317 for psoriasis. Compared to currently available therapies for autoimmunity, in which a portion of the immune system is either blocked or depleted, a fibroblast-based treatment aims to bring the body back into homeostasis through activation of the body's own internal biological healing process, which should result in a durable treatment that has significantly reduced side effects.

In the EAE rat model of MS, a single treatment of fibroblast spheroids resulted in a return to baseline on the EAE severity scale followed by long-term induction, as shown in the following figure. This was in contrast to treatment with adipose-derived MSCs that showed a slow, gradual decrease in the EAE severity score similar to control. To examine the potential mechanism of action on the immune system, the company found that fibroblast treatment results in expansion of regulatory T cells, which are a key component in maintaining homeostasis in the immune system, along with inhibition of reactive T cells and suppression of IL-17 expression. In addition, there was upregulation of anti-inflammatory cytokines IL-10, IL-1, and PD-L1. Lastly, there was significant remyelination detected in the cerebral cortex of EAE rats treated with fibroblasts.



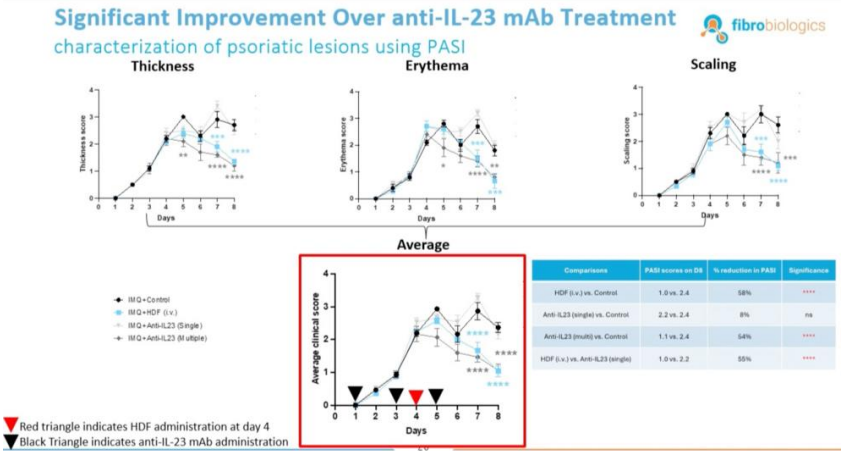
Source: FibroBiologics, Inc.

To examine the effect of fibroblast treatment in psoriasis, the company utilized mouse models of both moderate and severe disease. In moderate disease, the results showed that a single dose of intravenously administered fibroblasts resulted in a significant improvement in all aspects of the disease (upper figure). The lower figure shows that multiple treatments with fibroblasts resulted in a significant improvement in severe disease. This was accompanied by a reduction in pro-inflammatory cytokines (IL-23, TNF-α, IL-12p70) in the skin lesions.



Source: FibroBiologics, Inc.

The company also performed a comparison study using a leading anti-IL-23 monoclonal antibody that is approved for treating psoriasis. The following graphs show that a single administration of fibroblasts is just as effective as multiple doses of the anti-IL-23 antibody. Additional studies are currently underway comparing multiple doses of fibroblasts to multiple doses of the anti-IL-23 antibody. Skyrizi®, an anti-IL-23 monoclonal antibody, is forecast to generate over $11 billion in sales for the treatment of psoriasis in 2030 (EvaluatePharma).



Source: FibroBiologics, Inc.

Early-Stage Products

Artificial Thymus Organoid (ATO): This product is being developed for maintaining immune system homeostasis as individuals age. The thymus has an approximately 15.7-year half-life in humans, which means that by age 60 it has lost >90% of its functionality. Since the thymus is the "teaching center of the immune system", as individuals age and lose that function there is a reduced response to vaccination, increased risk of cancer, increased risk of autoimmune diseases, and an increased susceptibility to infections.

FibroBiologics is developing a fibroblast-based ATO in which cells from the thymus are combined with uniquely produced fibroblasts to create a T cell producing organoid. Early studies have shown that the manufacturing is scalable, it is transplantation ready in a short amount of time, there is durable fixation of the organoid for up to 60 days, and it can survive long-term cryopreservation. The organoid produces functional T cells within three weeks of culturing. These T cells include both regulatory T cells and Gamma-delta T cells. In addition, the T cells produced by the transplanted ATO have a diverse set of TCR-β chains.

Cancer Research Program: The company's cancer research program has multiple aims: i) reprogramming cancer-associated fibroblasts; ii) fibroblast-based delivery of tumor inhibitory agents; iii) induction of tumor vascular necrosis; and iv) producing organoid-based CAR-T and CAR-NK as potential cancer vaccines and therapeutics.

Financial Update

Secures $25 Million Financing

In December 2024, FibroBiologics announced it has entered into a Standby Equity Purchase Agreement (SEPA) with YA II PN Ltd., an investment fund managed by Yorkville Advisors Global, LP. The SEPA allows for FibroBiologics to sell up to $25 million in common stock to Yorkville over the next two years.

The financing will allow the company to advance its pipeline of fibroblast-based therapies targeting diabetic foot ulcers (DFUs), psoriasis, and multiple sclerosis, including the initiation of a Phase 1/2 trial of CYWC628 in patients suffering from DFUs in the second quarter of 2025 and the completion of pre-IND studies for its intravenously-administered fibroblast cell-based psoriasis candidate CYPS317 before the end of 2025.

As part of the agreement, Yorkville has agreed to advance the first $15 million available under the SEPA in three equal tranches in exchange for convertible promissory notes. The first two tranches have been advanced; the first $5 million upon closing and the second $5 million upon filing of a registration statement covering the resale of the shares issuable under the promissory notes. The third tranche of $5 million will be advanced following the effectiveness of the registration statement and receipt of shareholder approval. While the promissory notes are outstanding, FibroBiologics can sell up to an additional $10 million in common stock to Yorkville.

Conclusion

The Analyst Day presentation provided a clear picture of the potential for fibroblast-based therapies and we look forward to additional updates from the company throughout this year. With the financing in place, FibroBiologics is set to continue advancing its pipeline according to its previously announced timelines, including the initiation of a Phase 1/2 trial of CYWC628 in DFUs in the second quarter of 2025 and the completion of IND-enabling studies for its psoriasis candidate CYPS317 by year end 2025. We had already accounted for an increased share count in our financial model, thus our valuation remains at $11 per share.

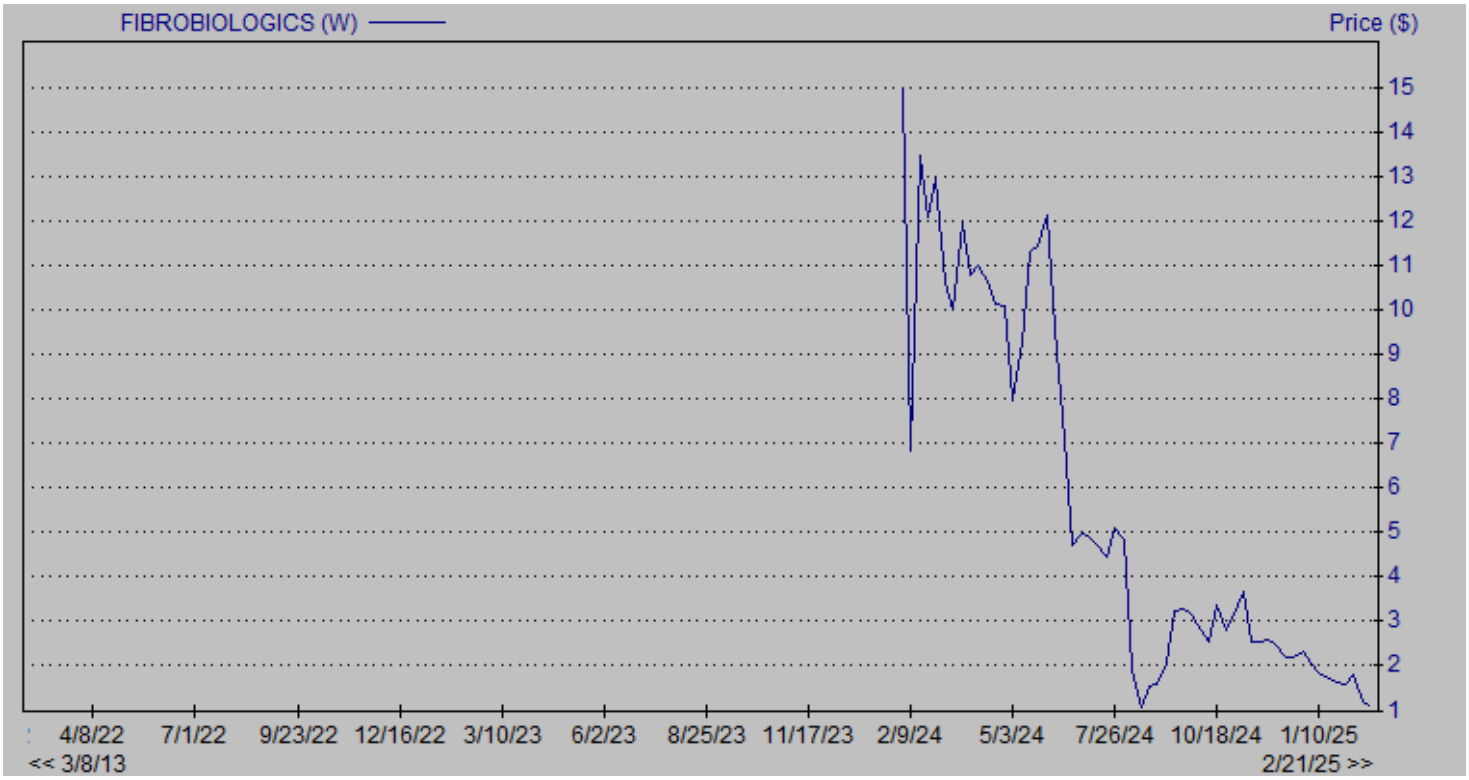
PROJECTED FINANCIALS

FibroBiologics, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
CybroCell	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CYMS101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CYWC628	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Psoriasis	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$2.4	$1.0	$1.0	$1.2	$1.0	$4.1	$6.0	$8.0
General & administrative	$6.5	$2.5	$2.2	$2.1	$1.9	$8.8	$7.5	$7.7
Operating Income	($8.9)	($3.5)	($3.2)	($3.4)	($2.9)	($12.9)	($13.5)	($15.7)
Non-Operating Expenses (Net)	($7.6)	($5.0)	$4.1	$2.9	$0.0	$2.0	$0.0	$0.0
Pre-Tax Income	($16.5)	($8.5)	$0.9	($0.5)	($2.9)	($11.0)	($13.5)	($15.7)
Deemed Dividend	$2.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($19.1)**	**($8.5)**	**$0.9**	**($0.5)**	**($2.9)**	**($11.0)**	**($13.5)**	**($15.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.68)**	**($0.27)**	**$0.03**	**($0.01)**	**($0.09)**	**($0.33)**	**($0.29)**	**($0.29)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	28.2	31.1	32.7	33.5	34.0	32.8	47.0	55.0

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

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HISTORICAL STOCK PRICE



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