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FibroBiologics, Inc.

(FBLG-NASDAQ)

FBLG: Poster Presentation Shows Potential for Fibroblast Therapy in Psoriasis…

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 (05/22/25)	$0.91
Valuation	**$11.00**

OUTLOOK

On May 14, 2025, FibroBiologics, Inc. (FBLG) announced financial results for the first quarter of 2025 and provided a business update. The company recently delivered a poster presentation highlighting preclinical results showing the potential for a fibroblast-based therapy in the treatment of psoriasis. The results showed fibroblast-based spheroids had therapeutic efficacy in both acute and chronic mouse models of psoriasis. FibroBiologics is planning to initiate a Phase 1/2 trial of its fibroblast-based spheroids candidate CYWC628 in diabetic foot ulcer (DFU) patients in the third quarter of 2025, with results expected in the first quarter of 2026.

SUMMARY DATA

52-Week High	**$12.96**
52-Week Low	**$0.81**
One-Year Return (%)	**-91.50**
Beta	**-0.25**
Average Daily Volume (sh)	**178,189**
Shares Outstanding (mil)	**38**
Market Capitalization ($mil)	**$35**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**20**
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)
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2026					0.0 E
2027					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$0.27 A	$0.03 A	-$0.01 A	-$0.11 A	-$0.34 A
2025	-$0.14 A	-$0.09 E	-$0.09 E	-$0.09 E	-$0.40 E
2026					-$0.31 E
2027					$0.31 E

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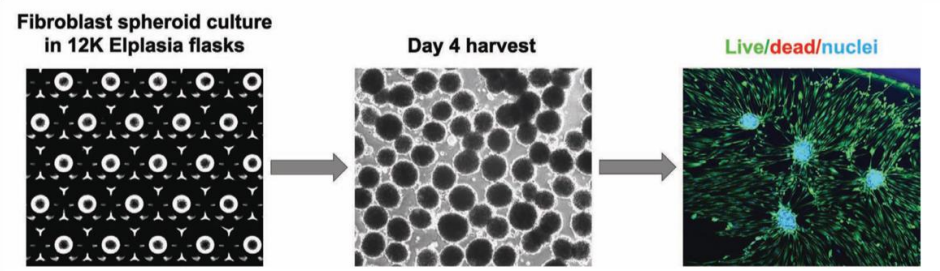
WHAT'S NEW

Business Update

Preclinical Psoriasis Data Presented at SID Annual Meeting

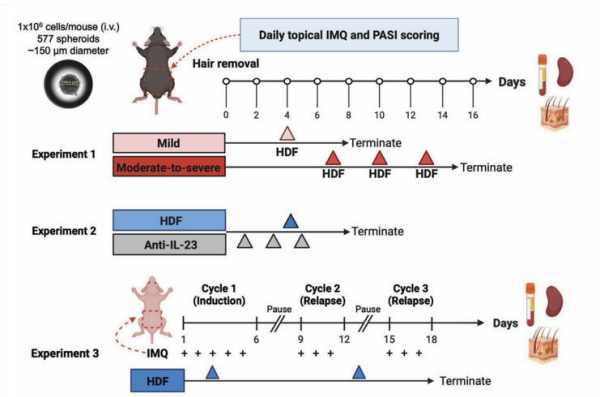
On May 16, 2025, FibroBiologics, Inc. (FBLG) announced a poster presentation at the Society for Investigative Dermatology (SID) Annual Meeting. The poster entitled "Immunomodulatory Potential of Human Dermal Fibroblast Spheroids in Psoriasis Therapy" can be viewed here (Fang *et al*., 2025).

The following image shows an overview of how the company's fibroblast-based spheroids are produced. After growing the cells in Elplasia® 12K Flask, which are specially designed with microcavities to enable the formation of similarly shaped spheroids. The spheroids are harvested following four days of growth, with the image on the right depicting the formation of the spheroids as tightly packed cells.



Source: Fang *et al*., 2025

The results of three different experiments were shared as part of the poster presentation. In the first experiment, single and multiple administrations of human dermal fibroblast (HDF) spheroids were tested in mouse models of mild and moderate-to-severe psoriasis. In experiment two, there was a comparative analysis of the therapeutic efficacy between HDF spheroids and anti-IL-23 treatment in a psoriasis model. In the third experiment, HDF spheroids were tested in a chronic-relapse psoriasis model. The HDF spheroids were administered intravenously for all studies. These experiments utilized imiquimod (IMQ), a toll-like receptor 7 and 8 ligand, in which topical application leads to rapid induction of psoriasis-like dermatitis (Jabeen *et al*., 2020).



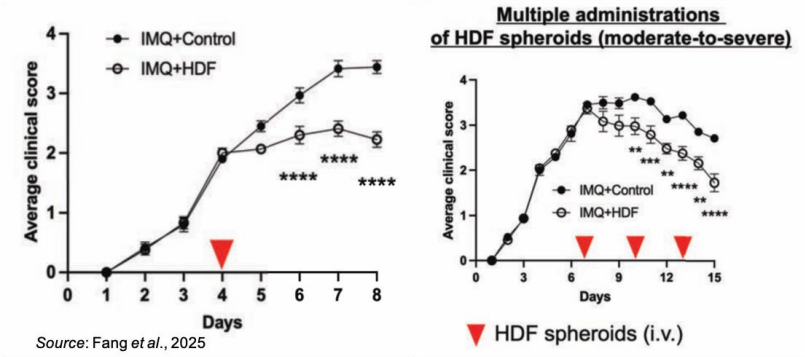
Source: Fang *et al*., 2025

Experiment 1

The following charts show the average clinical score over time for one administration of HDF spheroids (left image) or multiple administrations of HDF spheroids (right image). A single administration of HDF spheroids on day 4 stops the increase in clinical score while the control animals psoriasis continues to worsen. When

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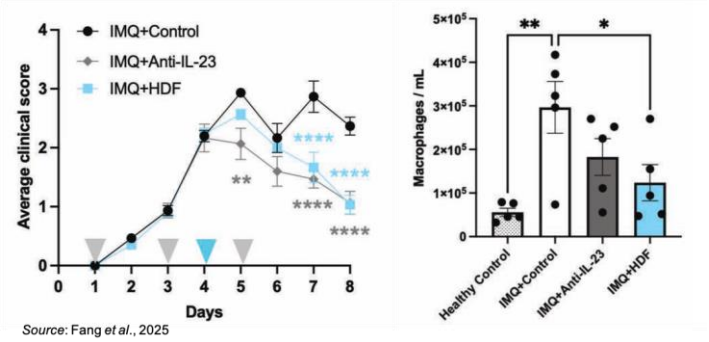
HDF spheroids are administered on Days 7, 10, and 13 the average clinical score decreases at a more rapid pace than control animals.



Source: Fang et al., 2025

Experiment 2

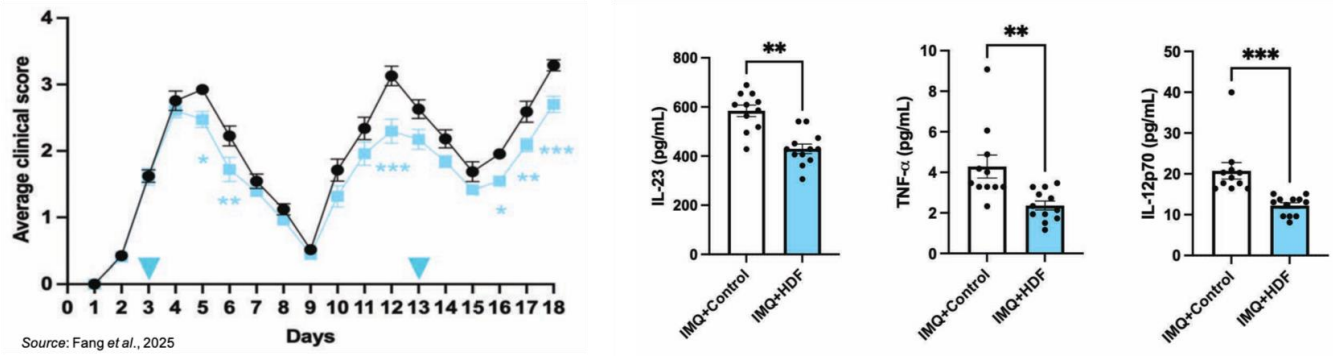
The results for this experiment showed that a single administration of HDF spheroids was just as effective as multiple administration of anti-IL-23 therapy in decreasing average clinical score (below left image), which included similar improvements in thickness score, erythema score, and scaling score. In addition, HDF spheroid therapy showed greater systemic efficacy in decreasing the macrophage count as compared to IL-23 therapy (below right image). The IL-23 targeted therapies for psoriasis include Skyrizi®, Tremfya®, and Ilumya®, with those three medicines generating over $10 billion in revenues in 2024 (EvaluatePharma).



Source: Fang et al., 2025

Experiment 3

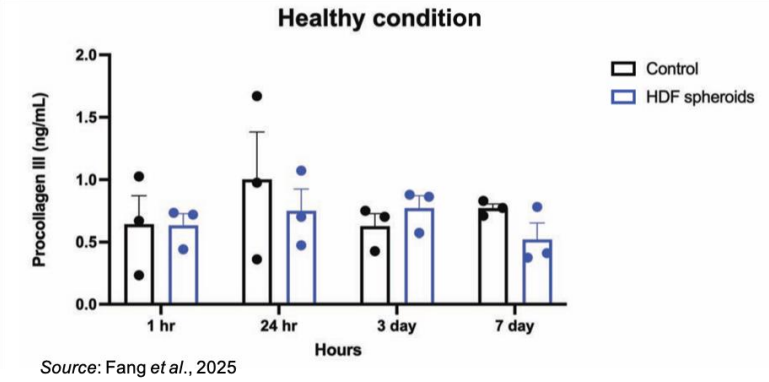
In the chronic-relapse psoriasis model, HDF spheroid administration resulted in a faster decrease in average clinical score and lowered the severity of the clinical score during the relapse phase. In addition, administration of HDF spheroids resulted in lower systemic levels of IL-23, TNF-a, and IL-12p70 compared to control animals.



Source: Fang et al., 2025

Fibrotic Effects

To determine if HDF spheroids promote fibrotic activity, HDF spheroids were administered to healthy mice, those with mild psoriasis, and those with moderate-to-severe psoriasis and the level of systemic procollagen III (P3NP) was determined. P3NP is a biomarker of active fibrosis activity. Importantly, HDF spheroid administration did not increase P3NP levels compared to control mice.



Source: Fang *et al.*, 2025

In summary, HDF spheroids were effective in treating psoriasis in both acute and chronic mouse models with no evidence of fibrotic activity as judged by P3NP levels. These results support testing HDF spheroids in the clinic for the management of psoriasis

Phase 1/2 Trial in Diabetic Foot Ulcers to Initiate in 3Q25

FibroBiologics is continuing preparations for a Phase 1/2 trial of CYWC628, a fibroblast-based spheroid product candidate, in patients suffering from diabetic foot ulcers (DFUs), which we anticipate initiating in the third quarter of 2025 and completing in the first quarter of 2026. Recent activities the company has accomplished to support the upcoming clinical trial include:

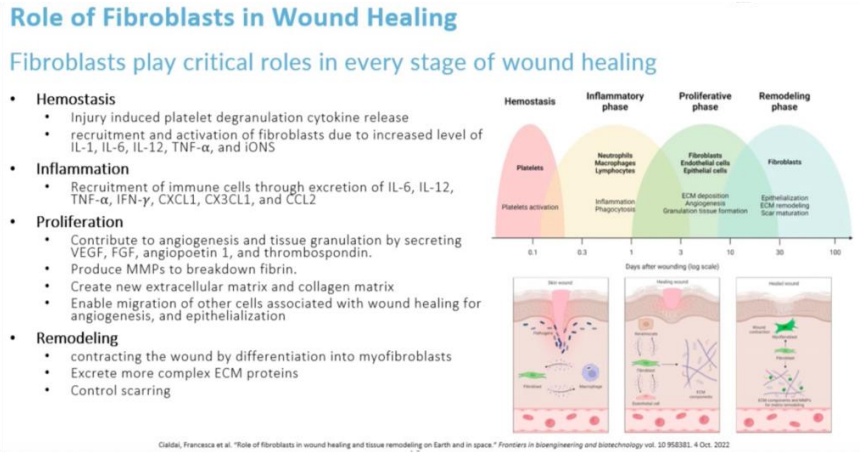
- In October 2024, FibroBiologics and Charles River Laboratories announced a master services agreement to develop and manufacture the company's therapeutic master cell bank, working cell bank, and fibroblast-based spheroids product CYWC628. In addition, the company announced the technology transfer for cGMP manufacturing was successfully completed along with feasibility studies evaluating the cell manufacturing processes. Based on the positive results of the feasibility studies, Charles River became the contract development and manufacturing organization (CDMO) to produce drug products for the upcoming Phase 1/2 for CYWC628.

- In February 2025, FibroBiologics and Charles River announced the completion of FibroBiologics' proprietary master cell bank, which will support the upcoming clinical trial of CYWC628. In addition, the cell bank, which was manufactured in accordance with cGMP, successfully passed all required safety testing.

- In September 2024, FibroBiologics announced it had engaged Southern Star Research to provide clinical research organization (CRO) services for the company in Australia, including preparation for the planned Phase 1/2 clinical trial of CYWC628 for the treatment of DFUs.

CYWC628 is being developed for the treatment of 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%).

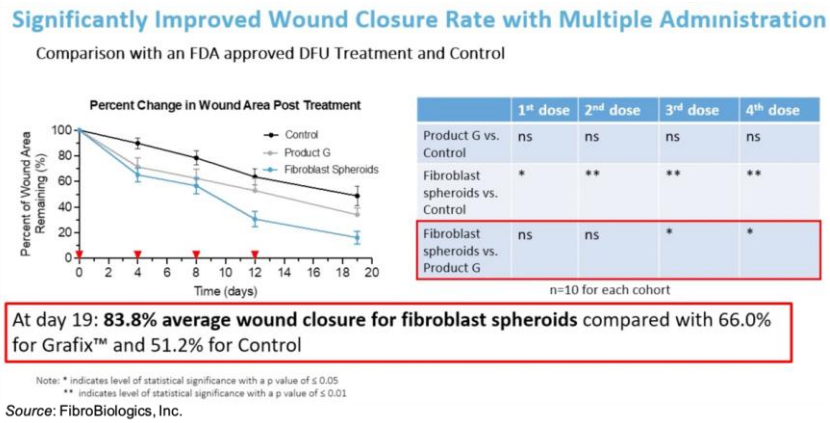
Fibroblasts have excellent therapeutic potential in the treatment of DFUs due to the critical role they play in every stage of wound healing, including hemostasis, inflammation, proliferation, and remodeling. Importantly, fibroblasts are the key cells that secrete extracellular matrix proteins that maintain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



Source: FibroBiologics, Inc.

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.



Source: FibroBiologics, Inc.

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.

Financial Update

On May 14, 2025, FibroBiologics announced financial results for the first quarter of 2025. As expected, the company did not report any revenues for the three months ending March 31, 2025. Research and development expenses were approximately $1.8 million in the first quarter of 2025, compared to approximately $1.0 million in the first quarter of 2024. The increase was primarily due to increased drug product expenses and other expenses to prepare for the Phase 1/2 clinical trial in DFU patients along with hiring of additional personnel. General and administrative expenses were approximately $2.8 million in the first quarter of 2025, compared to approximately $2.5 million in the first quarter of 2024. The increase was primarily due to additional personnel.

The company exited the first quarter of 2025 with approximately $8.7 million in cash and cash equivalents. As of May 13, 2025, FibroBiologics had approximately 38.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 43.6 million.

Conclusion

FibroBiologics continues to generate encouraging preclinical data for its fibroblast-based therapies, with the recent poster presentation highlighting the potential in the management of psoriasis. In the near-term, we anticipate the initiation of the Phase 1/2 clinical trial in DFUs to begin in the third quarter of 2025 and to conclude in the first quarter of 2026. This year, we also anticipate updates on the potential use of the CYWC628 master cell bank for use in manufacturing CybroCell™ for the treatment of degenerative disc disease along with the completion of pre-IND studies for CYPS317 for the management of psoriasis before the end of 2025. With no changes to our model our valuation remains at $11 per share.

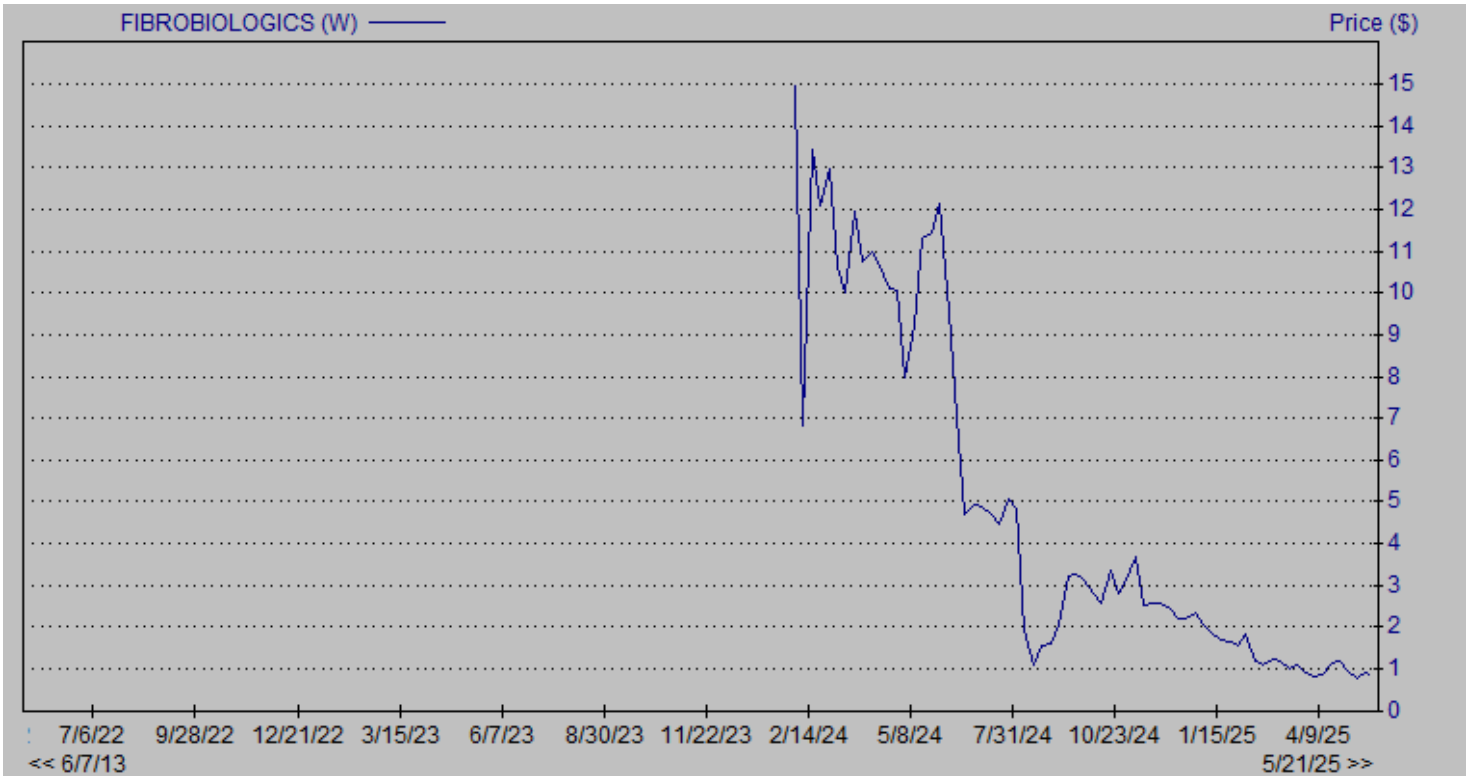
PROJECTED FINANCIALS

FibroBiologics, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 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	$4.5	$1.8	$1.2	$1.3	$1.4	$5.7	$6.5	$7.5
General & administrative	$9.2	$2.8	$2.1	$2.1	$2.2	$9.2	$9.0	$9.5
Operating Income	($13.7)	($4.5)	($3.3)	($3.4)	($3.6)	($14.9)	($15.5)	($17.0)
Non-Operating Expenses (Net)	$2.6	($0.4)	$0.0	$0.0	$0.0	($0.4)	$0.0	$0.0
Pre-Tax Income	($11.2)	($5.0)	($3.3)	($3.4)	($3.6)	($15.3)	($15.5)	($17.0)
Deemed Dividend	$0.0	$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	**($11.2)**	**($5.0)**	**($3.3)**	**($3.4)**	**($3.6)**	**($15.3)**	**($15.5)**	**($17.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.34)**	**($0.14)**	**($0.09)**	**($0.09)**	**($0.09)**	**($0.40)**	**($0.31)**	**($0.31)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	32.9	36.7	38.0	39.0	40.0	38.4	50.0	55.0

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

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