

MiMedx Group, Inc.

(MDXG - NASDAQ)

Third Quarter Results

Based on our multiple of earnings model and a 20% discount rate, MiMedx target price is approximately \$10.00 per share. Our methodology applies a 20x multiple of earnings to 2026 EPS, a 15x multiple to 2026 EBITDA and discounts a blend of the two approaches to generate a one-year target price.

Current Price (11/3/2021) **\$8.09**
Valuation \$10.00

OUTLOOK

MiMedx is a wound care and therapeutic biologics company, developing and distributing allografts. The company derives its products from human placental tissues processed using the Purion technology. MiMedx differentiates itself in the regenerative medicine market through the substantial library of supportive research for its products. The company's platform includes AmnioFix, EpiFix, EpiCord, EpiBurn, EpiCord Expandable, AmnioCord and AmnioFill. The products are derived from placental and umbilical cord tissue.

In addition to its marketed products, MiMedx is developing assets in knee osteoarthritis (KOA) and potentially other line extensions in regenerative medicine and wound care. Phase III clinical trials are anticipated for AmnioFix injectable in KOA and other indications which was subject to enforcement discretion prior to June 2021.

Legal matters are near conclusion with a majority of issues resolved and major related costs largely behind the company.

We forecast continued growth in commercialized products and success in the development pipeline that will drive topline growth. International opportunities include Japan, the UK and Germany which have approved MiMedx products and are in process to determine reimbursement.

SUMMARY DATA

52-Week High **\$15.99**
 52-Week Low **\$5.30**
 One-Year Return (%) **23.3**
 Beta **1.95**
 Average Daily Volume (sh) **1,075,187**

Shares Outstanding (mil) **112**
 Market Capitalization (\$mil) **906**
 Short Interest Ratio (days) **3.22**
 Institutional Ownership (%) **59.5**
 Insider Ownership (%) **2.77**

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 2020 Estimate **N/A**
 P/E using 2021 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Average**
 Type of Stock **Small-Growth**
 Industry **Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2020	\$61.7 A	\$53.6 A	\$64.3 A	\$68.5 A	\$248.2 A
2021	\$60.0 A	\$68.2 A	\$63.1 A	\$60.6 E	\$251.8 E
2022					\$288.1 E
2023					\$339.9 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2020	-\$0.04 A	-\$0.08 A	-\$0.18 A	-\$0.15 A	-\$0.46 A
2021	-\$0.08 A	-\$0.01 A	-\$0.02 A	-\$0.04 E	-\$0.15 E
2022					\$0.17 E
2023					\$0.45 E

WHAT'S NEW

Third Quarter 2021 Financial and Operational Results

On November 2, 2021, MiMedx Group, Inc. (NASDAQ: MDXG) filed its 3Q:21 Form 10-Q with the SEC and issued a [press release](#) summarizing its financial and operational results. A conference call and [webcast](#) were held the following morning to communicate additional detail to analysts and investors.

Highlights for the third quarter, ended September 30th, and to-date include:

- Cato Laurencin, MD, PhD, receives NAACP Spingarn Medal - July 2021
- Marion Snyder [promoted](#) to Chief of Staff, Senior Vice President, Government Affairs - August 2021
- [Publication](#) in *Journal of Wound Care* - August 2021
- SEC shelf registration statement [filing](#) and [result](#) - August/September 2021
- Interim [results](#) from Phase IIb knee osteoarthritis - September 2021
- Topline [results](#) from Phase III plantar fasciitis - September 2021
- Two studies [demonstrating](#) potential of mdHACM in OA and tendinopathy processes - November 2021

Revenues and net loss for the quarter were \$63.1 million and (\$2.34) million, respectively, and net loss available to common stockholders was (\$3.91) million. Net loss per share was (\$0.02) and net loss per share to common stockholders, which recognizes the dividend paid to Series B convertible holders, was (\$0.04). These results compare to net loss of (\$0.18) and (\$0.48) at the end of the third quarter 2020, respectively.¹

For the third quarter ending September 30, 2021, compared to the same ending September 30, 2020:

- Reported revenues were \$63.1 million, down 1.9% from \$64.3 million. Revenue decrease in Section 351 product was all but offset by organic growth in advanced wound care offerings;
- Gross margin was consistent between the periods at 84%;
- SG&A was \$46.3 million, down 3.7% from \$48.0 million driven by lower professional fees on legal and other matters, offset by increases in travel expenses compared to restricted travel during the pandemic;
- Investigation, restatement and related expenses were \$3.2 million, down 73.6% from \$12.0 million as expenses decline with the resolution of legal proceedings relating to former officers and directors;
- R&D expenses were \$4.4 million, increasing 29.5% from \$3.4 million, reflecting increases in personnel costs, driven by increases in headcount to support clinical research efforts;
- Operating income was (\$1.1) million vs (\$9.7) million;
- Interest expense was (\$1.0) million versus (\$1.5) million;
- Net loss was (\$2.3) million versus (\$19.4) million, or (\$0.02) per share versus (\$0.18) per share;
- Net loss available to common stockholders was (\$3.9) million vs (\$52.0) million or (\$0.04) and (\$0.48).

As of September 30, 2021, cash stood at \$90.6 million. Debt was carried on the balance sheet at \$48.0 million. Free cash flow for the quarter was \$5.7 million compared to cash consumed of (\$5.3) million in the prior comparable period on lower net loss. Adjusted EBITDA as calculated by the company which adds back costs incurred related to the investigation and restatement and share based compensation was \$6.8 million which compares to prior year amount of \$6.9 million. EBITDA calculated by the company and Zacks was \$41,000.

Topline Results from Phase IIb KOA and Phase III PF

On September 13, 2021, MiMedx [reported](#) results from its Phase IIb Knee Osteoarthritis (KOA) study and topline results from its Phase III Plantar Fasciitis (PF) study. Six-month efficacy data from the Phase IIb KOA study interim results did not meet primary endpoints. Upon review of the Phase III PF data, management concluded that the results did not support a BLA filing. Management will discuss the data with the FDA as allowed under the Regenerative Medicine Advanced Therapy (RMAT) process. AmnioFix Injectable [received](#) RMAT designation for KOA in

¹ Note that shares outstanding is calculated using shares provided on income statement whereas shares outstanding on page 1 of this report include Series B convertible preferred stock as converted. Series B convertible preferred stock is mandatorily convertible into shares.

2018, which includes benefits of Fast Track and Breakthrough Designation programs. Upon further analysis by 3rd party biostatisticians provided in the third quarter earnings release, MiMedx updated investors with the statistical significance for the pre-interim analysis for the primary endpoints of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Total, WOMAC Pain, and WOMAC Function scores. This analysis included the first 190 patients and generated p-values of less than 0.05 for the three month observation and p-values less than 0.01 for the six month observation for each of the categories. However, as reported in the September 13th release, when the larger population (N=446) was reviewed, the results as a whole did not achieve statistical significance.

Phase IIb Knee Osteoarthritis

Topline results from an interim analysis at six months for the Phase IIb trial in KOA ([NCT03485157](#)) did not meet primary endpoints of [Visual Analog Scale](#) (VAS) for Pain or Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index. Efficacy measures differed between patient cohorts evaluated before and after a blinded interim analysis performed mid-2019. This anomaly has prompted management to pursue further confirmatory studies in the indication. Micronized dehydrated human amnion chorion membrane (mdHACM) was well tolerated with no significant adverse events or serious adverse events. Trial enrollment included 466 patients between the ages of 21 to 80 years. Subjects presented osteoarthritis grade 1 to 3 on the Kellgren Lawrence scale and a VAS for Pain score greater than 45. A lower-than-expected participant dropout led to final enrollment of 446 patients. The trial's 12-month safety visit follow up was completed in October 2021, with a six-month open-label extension to follow. A safety readout is also expected to be provided during the next presentation to stakeholders. MiMedx will provide additional detail on the trial at its announced December 7th virtual R&D / analyst day.

Exhibit I - Summary Phase IIb KOA Topline Interim Results²

Assessment	TOTAL TRIAL (446 PATIENTS)	Pre-Interim Analysis (190 patients)	Post-Interim Analysis (256 patients)
VAS	Not significant	Not significant	Not significant
WOMAC – Total	Not significant	Significant	Not significant
WOMAC – Pain	Not significant	Significant	Not significant
WOMAC – Function	Not significant	Significant	Not significant

Though not statistically significant, the topline analysis trended toward potential treatment efficacy, warranting further investigation. Differences were observed between patients enrolled prior to the study's initial blinded interim analysis and those enrolled after. Patients in the pre-interim analysis cohort demonstrated greater improvement in WOMAC-Total, WOMAC-Pain and WOMAC-Function scores and actually achieved statistical significance at both three- and six months. Patients in the post-interim analysis group were more difficult to differentiate as both treatment and placebo groups experienced positive responses. Analysis of VAS endpoint was not statistically differentiable in either pre- or post-interim analysis cohorts at either three- or six-month timepoints.

MiMedx expects that, based on the interim analysis, two Phase III studies in KOA will be necessary to file a BLA and it plans to meet with the FDA to discuss next steps. Endpoints will likely include the WOMAC scores and potentially imaging of affected joints using MRI or X-ray. When final data are available, we anticipate meetings with the FDA under RMAT, where trial design will be determined. Pending guidance from the FDA, MiMedx will update investors on timing as future activities become clear. Management plans further research to understand the underlying disease process in KOA, mdHACM's potential benefit to cartilaginous tissue, and understanding mdHACM's mechanism of action.

Phase III Plantar Fasciitis Topline

MiMedx' [trial](#) in Plantar Fasciitis did not achieve statistical significance in its primary efficacy endpoint of change in VAS for Pain at 90 days. MiMedx will not pursue a BLA for mdHACM in PF and will prioritize the KOA program. mdHACM was found safe and well tolerated in this study with no significant adverse events. Both treatment and placebo groups showed improvement in VAS Pain and Foot Function Index Revised (FFI-R) scores.

² MDXG Corporate Presentation September 2021

The Phase III study was a prospective, double-blind, randomized controlled trial of a single injection of 40 mg of mdHACM into the plantar fascia as compared to saline placebo. The trial enrolled 277 patients between the ages of 21 and 79 years with plantar fasciitis diagnosed for greater than or equal to one month and less than or equal to 18 months. Patients included had a VAS Pain score of greater than or equal to 45. Patients had been treated for greater than or equal to 1 month (30 days) using general modalities such as rest, ice, compression, elevation stretching, NSAIDs, or orthotics. The primary endpoints were change in VAS for Pain at 90 days and incidence of related adverse events at 180 days, serious adverse events, and unanticipated events during the first 12 months post-injection. Secondary endpoints included self-reported responses to the Foot Function Index – Revised (FFI-R) at 90 days.

Filing of Shelf Registration Statement

On August 27, MiMedx announced that it [filed](#) a Shelf Registration Statement with the SEC, and on September 8th, it announced that the filing had become effective, allowing MiMedx to sell up to \$350 million of various types of securities over the next three years (until September 2024). Despite the filing, we and management expect the company to have sufficient cash to fund its R&D objectives internally. MiMedx anticipates being cash flow positive on a normalized R&D spend basis in the next few quarters. With over \$90 million in cash available, we see more than sufficient funds to achieve the company's research and development goals.

Marion Snyder promoted to Chief of Staff, Senior Vice President, Government Affairs

On August 12, 2021, MiMedx [announced](#) that Marion Snyder was promoted to Chief of Staff, Senior Vice President, Government affairs. In this position, Ms. Snyder will oversee strategic, cross-functional projects, and drive the integration, effectiveness, and efficiency of decision making throughout MiMedx to advance multiple, company-wide initiatives. Snyder will continue to serve as co-chair of the Inclusion and Diversity Council, and as an important voice for MiMedx's government affairs and patient advocacy efforts.

Publications

Osteoarthritis and Cartilage Open

On November 1st, MiMedx announced two publications, one in *Osteoarthritis and Cartilage Open*, and the other in the *Journal of Biomedical Materials Research, Part B*. The first [study](#), entitled "Human amniotic membrane modulates Wnt/ β -catenin and NF- κ B signaling pathways in articular chondrocytes in vitro", identified a novel mechanism of action of micronized dHACM (mdHACM) where it regulates the process of human articular chondrocyte degradation. Chondrocytes are the primary cell type in articular cartilage. The data support mdHACM as a candidate for treatment of osteoarthritis and its potential as a disease modifying agent.

Journal of Biomedical Materials Research, Part B

The second [publication](#), entitled "Dehydrated human amniotic membrane regulates tenocyte expression and angiogenesis *in vitro*: Implications for a therapeutic treatment of tendinopathy", was in the *Journal of Biomedical Materials Research, Part B*, and examined chronicity and outcomes following tendon injury attributed to prolonged inflammation and hypervascularity. *In vitro* experiments evaluated mdHACM as a treatment for tendinopathy, in a model based on the same. The experiments identified specific mechanisms responsible for countering these disease processes.

Journal of Wound Care

On August 17, 2021, MiMedx [announced](#) the publication of its peer reviewed study in the *Journal of Wound Care*. The study investigated the impact of Advanced Treatment using all high-cost skin substitute products in lower extremity diabetic ulcers. The study was based on data from the Medicare Limited Dataset featuring data from October 2015 to October 2018, and evaluated outcomes in patients receiving Advanced Treatment versus those not using the same. It was found that Advanced Treatments could lead to a 42% reduction in major and minor amputations and all related costs compared to their non-advanced counterparts. Furthermore, the data underscored the importance of early treatment with regular intervals and defined treatment guidelines.

Cato T. Laurencin, MD. Ph.D., to Receive Historic NAACP Spingarn Medal

On July 14, 2021, MiMedx [announced](#) that the NAACP would present Dr. Cato Laurencin, member of MiMedx' Board, with its most prestigious honor, the Spingarn Medal. Dr. Laurencin is the Van Dusen Distinguished Endowed Professor at the University of Connecticut. Dr. Laurencin will be honored for his accomplishments in the fields of tissue regeneration, biomaterials, nanotechnology and regenerative engineering, a field that he founded. He received the Spingarn Medal at the NAACP's 112th Annual Convention. Dr. Laurencin is an International Fellow

in Biomaterials Science and Engineering, received the Founders Award from the Society for Biomaterials, is the first surgeon in history to be elected to all four national academies³ and has over 500 publications and patents. Dr. Laurencin also received the National Medal of Technology and Innovation.

Company Milestones

- IND / IDE submission for multiple wound care indications – As of August 2021:
 - Chronic cutaneous ulcers (AmnioFix) - IND Cleared
 - Surgical incisions (AmnioFix) – IND Cleared
 - Soft tissue defects (AmnioFill) – IND Filed
- Conclusion of enforcement discretion – May 2021
- Regulatory approval for EpiFix in Japan – June 2021
- Phase IIa KOA trial completion – April 2021
 - Final analysis & database lock – 2H:21
 - Final safety follow up – October 2021
 - Generation of full data set – 2H:21
 - End of Phase II meeting with FDA – 2H:21
- [Update](#) at HCW following PF & KOA topline – September 2021
- Analyst and investor R&D day – December 7, 2021
- Launch of Epifix in Japan – mid-2022

Summary

MiMedx reported results for the third quarter 2021. Revenues of \$63.1 million were ahead of our expectations and represented the first full quarter following the end of enforcement discretion. Ignoring the impact from Section 351 enforcement discretion-related product, sales increased 13%, continuing the strong trend observed in the first half of the year in part due to sales in the newly defined category of surgical recovery applications. Cash flow was another bright spot, with \$5.7 million in free cash flow generated. While lower than trend R&D contributed to the positive cash flow, we anticipate higher sales and better controlled costs will contribute to more improvements in 2022. Based on the strong performance in the quarter we increase our model's revenue estimates and raise anticipated selling costs. We reduce our research and development expenses to reflect anticipated normalized trends in this line item. While these changes reduce earnings in the short term, we believe these short and long term investments will improve revenues overall.

The big news during the quarter was the topline readout from the PF and KOA trials. Despite favorable early results in the Phase II PF study and interim results in the Phase IIb KOA study, both efforts missed their intended mark. MiMedx is now adjusting its future approach and will abandon the PF program and modify the KOA program. Next steps for the company include meetings with the FDA to identify a path forward as there has been substantial data demonstrating a benefit for KOA patients using mdHACM. The MiMedx team is analyzing available data to understand what influenced the changes in outcomes from earlier evaluations. More details on the KOA trial and what to expect for this indication going forward will be provided at the upcoming analyst day on December 7th. The better than expected third quarter results should be followed by further growth in 2022 with line extension products such as Epicord Expandable, continued penetration into surgical recovery applications and geographical reach into Japan and other international markets.

MiMedx holds sufficient cash on its balance sheet to reach steady state positive cash flows and earnings without additional capital raises. We continue to see full year positive earnings by 2022 and substantial growth over the next several years which will provide the firm substantial financial flexibility to optimize its capital structure. We maintain our price target of \$10.00 per share.

See our [initiation](#) on MiMedx for an in-depth discussion of MiMedx' technologies and products, our investment thesis, and discussion of recent events and milestones.

³ National Academy of Sciences, National Academy of Engineering, National Academy of Medicine and National Academy of Inventors

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement⁴

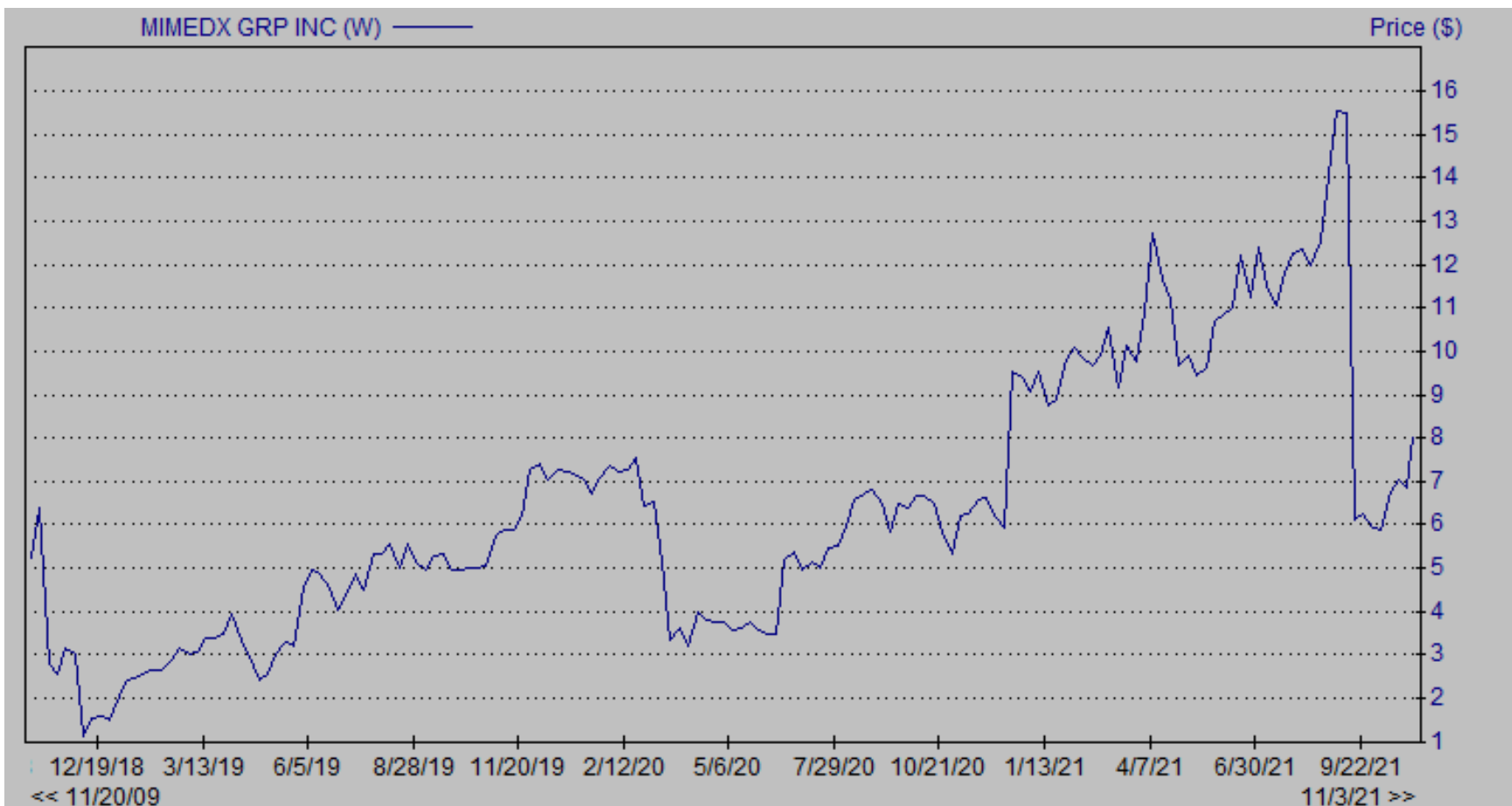
MiMedx Group, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
Total Revenues (\$US '000)	\$248,234	\$59,967	\$68,165	\$63,074	\$60,620	\$251,826	\$288,089	\$339,945
YOY Growth	-17%	-3%	27%	-2%	-12%	1%	14%	18%
Cost of Goods Sold	\$39,330	\$9,641	\$12,760	\$10,129	\$9,699	\$42,229	\$46,094	\$54,391
Product Gross Margin	84.2%	83.9%	81.3%	83.9%	84.0%	83.2%	84.0%	84.0%
Selling, general & administrative	\$181,022	\$45,404	\$53,599	\$46,289	\$46,820	\$192,112	\$193,000	\$194,930
Investigation, restatement etc.	\$59,465	\$7,196	(\$2,062)	\$3,170	\$0	\$8,304	\$0	\$0
Research & development	\$11,715	\$4,339	\$4,063	\$4,368	\$8,000	\$20,770	\$20,000	\$20,000
Amortization of intangible assets	\$1,073	\$239	\$215	\$193	\$272	\$919	\$1,088	\$1,088
Impairment of intangible assets	\$1,027	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Income from operations	(\$45,398)	(\$6,852)	(\$410)	(\$1,075)	(\$4,171)	(\$12,508)	\$27,907	\$69,536
Operating Margin	-18%	-11%	-1%	-2%	-7%	-5%	10%	20%
Interest income, net	(\$7,941)	(\$1,472)	(\$1,371)	(\$963)	(\$875)	(\$4,681)	(\$3,500)	(\$3,500)
Other income, net	(\$8,204)	\$0	(\$3)	\$0	\$0	(\$3)	\$0	\$0
Pre-Tax Income	(\$61,543)	(\$8,324)	(\$1,784)	(\$2,038)	(\$5,046)	(\$17,192)	\$24,407	\$66,036
Provision for Income Tax	\$12,259	(\$58)	\$5	(\$301)	\$0	(\$354)	\$0	\$0
Tax Rate	-19.9%	0.0%	0.0%	0.0%	0.0%	2.1%	0.0%	0.0%
Net Income	(\$49,284)	(\$8,382)	(\$1,779)	(\$2,339)	(\$5,046)	(\$17,546)	\$24,407	\$66,036
Net Margin	-20%	-14%	-3%	-4%	-8%	-7%	8%	19%
Reported EPS	(\$0.46)	(\$0.08)	(\$0.01)	(\$0.02)	(\$0.04)	(\$0.15)	\$0.17	\$0.45
YOY Growth		70.9%	-83.8%	-88.2%	-70.5%	-67%	-214%	159%
Basic Shares Outstanding	108,257	109,401	110,277	110,717	112,320	116,130	120,243	135,258
Fully Diluted Shares	108,257	141,924	140,277	141,375	141,620	141,299	141,800	148,193

Source: Company Filing // Zacks Investment Research, Inc. Estimates

⁴ Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart⁵



⁵ Source: Zacks Research System

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