

## MiMedx Group, Inc.

(MDXG - NASDAQ)

### Pre-Interim Puzzle Solved

Based on our multiple of earnings model and a 20% discount rate, MiMedx target price is approximately \$12.00 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 (12/10/2021)

\$6.97

Valuation

\$12.00

### 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, AmnioFill, AmnioEffect & Placental Collagen Matrix. 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 (%)	17.7
Beta	1.96
Average Daily Volume (sh)	826,438

Shares Outstanding (mil)	112
Market Capitalization (\$mil)	781
Short Interest Ratio (days)	5.16
Institutional Ownership (%)	57.5
Insider Ownership (%)	2.76

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
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#### Risk Level

Above Average

#### Type of Stock

Small-Growth

#### Industry

Med-Biomed/Gene

### ZACKS ESTIMATES

#### Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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	\$62.3 E	\$253.5 E
2022					\$290.0 E
2023					\$342.2 E

#### Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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	-\$0.03 E	-\$0.14 E
2022					\$0.18 E
2023					\$0.46 E

## WHAT'S NEW

### Investor Day

On December 7, 2021, MiMedx Group, Inc. (NASDAQ: MDXG) held a Virtual Investor Day for the first time in four years. The Investor Day was held via [webcast](#) and featured a number of distinguished Key Opinion Leaders (KOLs). The primary concern since the September 13<sup>th</sup> topline data report for Knee Osteoarthritis (KOA) was addressed in the presentation and a path forward for the KOA program was provided. Based on an extensive review of the data, MiMedx determined that the age of the micronized dehydrated human amnion chorion membrane (mdHACM) product impacted its potency, obscuring clinical efficacy results from the trial. The analysis allows us to conclude that product less than two years old should provide a statistically significant benefit as seen in the first patients enrolled in the Phase II KOA trial.

Other key takeaways from the Investor Day include:

- Interim result details including p-values from Phase IIb KOA study supporting registrational trials;
- Root cause analysis for Phase Iib KOA endpoint miss;
- Expected 2022 start to two Phase III trials for KOA;
- KOA Biologics License Application (BLA) filing anticipated in late 2025;
- Outlined commercial business strategy for double-digit growth;
- Updated net sales outlook for 2021.

The event featured two segments and the following MiMedx representatives and Key Opinion Leaders (KOLs):

- KOA Key Findings & Path Forward;
  - Robert B. Stein, M.D., Ph.D., EVP, Research and Development, MIMEDX;
  - Michelle Massee, AVP, Product Development, MIMEDX;
  - Thomas M. Mick, M.D., Medical Director, Clinical Development, MIMEDX;
  - Vibeke Strand, M.D., Stanford University School of Medicine;
  - Kris J. Alden, M.D., Ph.D., Orthopedic Surgeon, Hip, Knee & Shoulder Reconstruction;
- Commercial Business Growth Strategy & Market Opportunity;
  - Rohit Kashyap, Ph.D., EVP, Chief Commercial Officer, MIMEDX;
  - John Harper, Ph.D., SVP, Research & Product Development, Chief Technology Officer, MIMEDX;
  - William H. Tettelbach, M.D., Principal Medical Officer, Head of Medical Affairs, MIMEDX;
  - Bidhan B. Das, M.D., Colon, Rectal & General Surgeon;
  - Caroline Clarke, M.D., Plastic, Reconstructive & Cosmetic Surgeon;
  - Jonathan Labovitz, D.P.M., Western University of Health Sciences;

### KOA Key Findings & Path Forward

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. However, pre-interim results from 190 patients did achieve statistical significance at three and six months for WOMAC<sup>1</sup> Pain, Function and Total measures, prompting further analysis.

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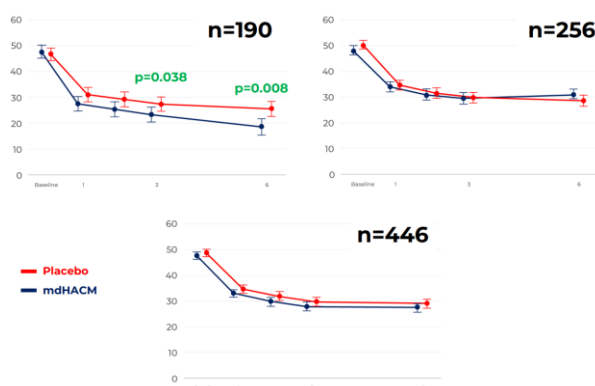
<sup>1</sup> Western Ontario and McMaster Universities Osteoarthritis Index

### Exhibit I - MiMedx Phase IIb KOA Interim P-values<sup>2</sup>

Measure	Three Month	Six Month
WOMAC Pain	3.2%	0.9%
WOMAC Function	4.6%	0.9%
WOMAC Total	3.8%	0.8%

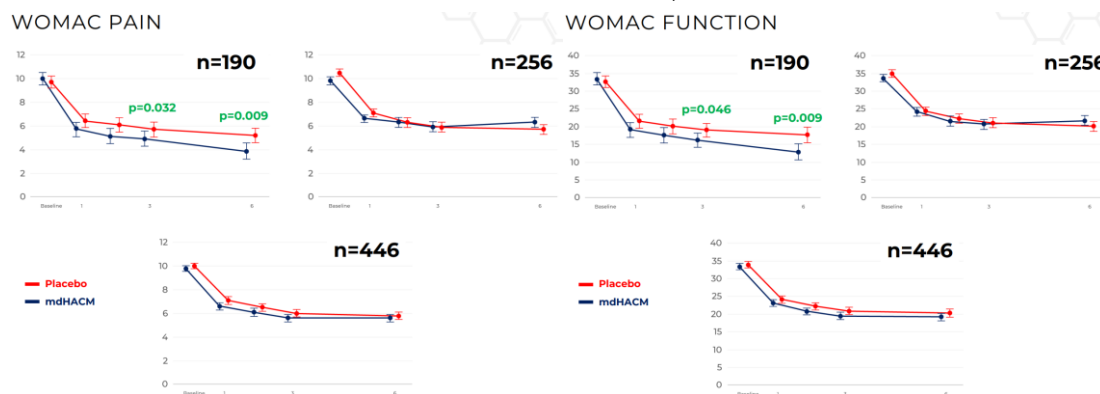
The statistically significant results of patients enrolled pre-interim analysis were depicted in graphs, and compared against the latter 256 patients and the 446 total enrollment for the Phase IIb.

### Exhibit II - Phase IIb KOA WOMAC Total, Cohorts<sup>3</sup>



The graphs depict a statistical differentiation in the 190-patient pre-interim cohort that is apparent at three months and widens at six months. This differentiation is absent in the 256 patients that followed (post-interim analysis enrollees), and the 256 patients obscure overall results when combined with the pre-interim 190 for the 446 total. The trends are consistent with WOMAC Pain and WOMAC Function as well.

### Exhibit III - KOA Phase IIb WOMAC Pain, WOMAC Function<sup>4</sup>



When analyzing for drivers of the disparity, the pandemic, sites, use of ultrasound, patient demographics (age, gender, KOA severity) were all examined in an intensive review; however, these factors did not explain the trend. After a comprehensive review, MiMedx found that potency of the clinical batch of mdHACM prepared prior to the start of the trial had waned through the trial's duration, with the length of the study exacerbated by interruption and delay due to the pandemic. Participants at the end of the trial received product that had been manufactured 2-3 years prior to administration. In contrast to its use in the clinic, when AmnioFix Injectable was marketed, product was consumed within a short period of time after its manufacture. Investigators elected to use a single batch for the entire clinical trial in order to maintain a high level of consistency for dosing. Now aware of the issue, management is confident that this can be addressed by ensuring that product is used within its expected life in the two registrational trials planned for 2022. The two trials are expected to cost \$15 million each, or \$10 million per year for the next three years. The trials plan to enroll 400-500 patients in each study, and MiMedx will pursue a BLA application for

<sup>2</sup> Compiled by Zacks analyst

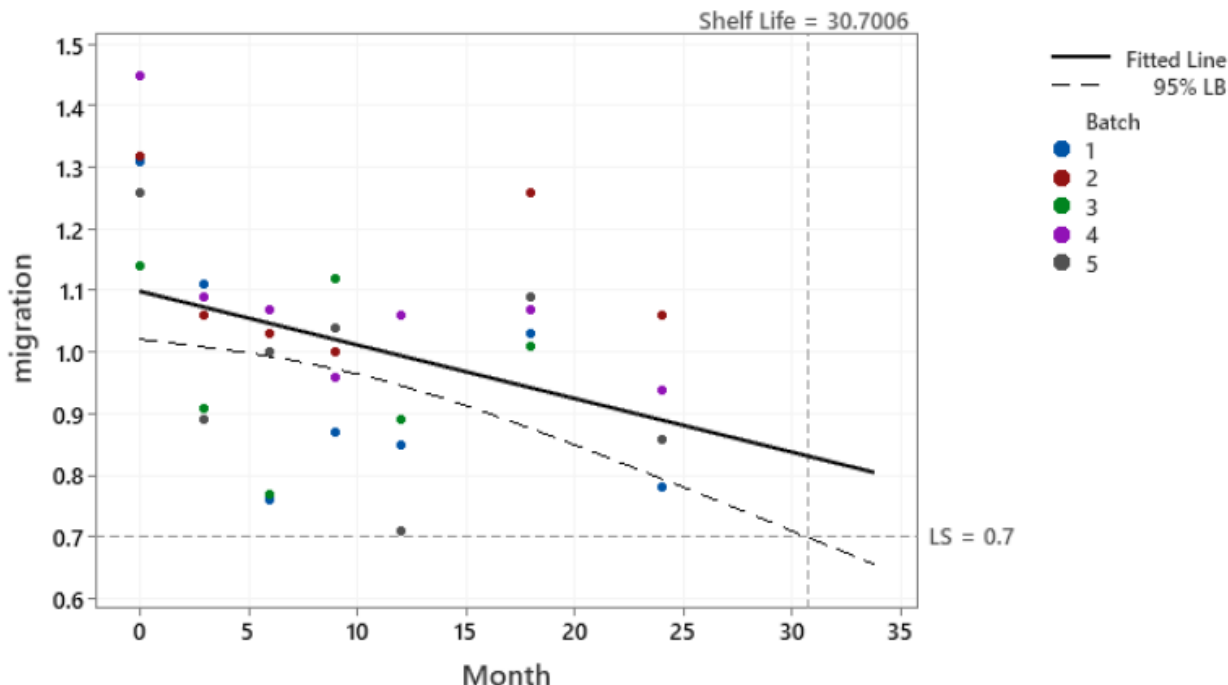
<sup>3</sup> MDXG Investor Day Presentation, December 2021

<sup>4</sup> MDXG Investor Day Presentation, December 2021

mdHACM in KOA in late 2025. Primary endpoints for the two studies will be based on WOMAC and will not include VAS,<sup>5</sup> as WOMAC is superior to VAS in capturing the chronicity of KOA, and has become the favored measure in the field.

The potency of the product was corroborated with shelf-life data showing a similar trend. Importantly, the data showed that a single 40mg injection of mdHACM produced benefits for at least 6 months, with potential to have a lasting effect for even longer.

Exhibit IV – Shelf Life Plot for All Batches<sup>6</sup>



Management then highlighted MiMedx' understanding of the pathways implicated in mdHACM: Wnt, nuclear factor Kappa beta (NF- $\kappa$ B), and transforming growth factor beta. These three key pathways are one of potentially many that mdHACM modulates through its diverse molecular therapeutic profile. Given these pathways, and with some of the *in vivo* work that was explained by Michelle Massee, MiMedx' AVP, Product Development, could lead potentially to **disease modifying** labeling. mdHACM does not simply mask symptoms, but modulates cellular pathways that could stop or even reverse cartilage degeneration. Anecdotal evidence from physicians that used AmnioFix Injectable further supported the potential for mdHACM in KOA. Dr. Kris Alden, MD, PhD was a KOL guest who spoke directly to his experience with patients and using AmnioFix Injectable.

#### Phase IIb Knee Osteoarthritis

As a brief recapitulation of the Phase IIb KOA trial, we recall that 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 prompted management to pursue further confirmatory studies in the indication. 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 included had osteoarthritis grade 1 to 3 on the Kellgren Lawrence scale and a VAS for Pain score greater than 45. Due to a lower-than-expected participant dropout, the trial has already achieved an adequate number of patients to assess the primary endpoint. The final enrollment totaled 446 patients.

#### Growth Strategy & Market Opportunity

Following a brief intermission, MiMedx' Investor Day transitioned to presentation and discussion of MiMedx' outlook on commercial growth and potential markets, led by MiMedx' EVP and Chief Commercial Officer, Rohit Kashyap, PhD.

<sup>5</sup> Visual Analog Scale, a scale measuring the subject's perceived pain over the past 24 hours

<sup>6</sup> MDXG Investor Day Presentation, December 2021. LS = Lower Specification. Curve regression:  $1.10 - 0.00871$  per month.

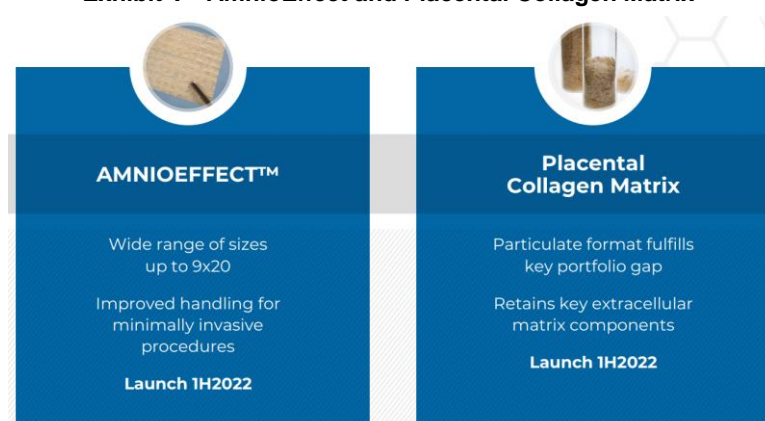
Management highlighted three areas of growth potential:

- Advanced wound care;
  - Diabetic foot ulcers;
  - Venous leg ulcers;
  - Pressure ulcers;
  - Complex wounds;
- Surgical recovery;
  - Tissue augmentation;
  - Barrier properties;
  - Surgical closure;
- International markets
  - Japan
  - Europe
- New Products
  - AmnioEffect (1H:22 launch)
  - Placental Collagen Matrix (1H:22 launch)

The advanced wound care market could represent 7-8% growth for MiMedx, and international and new products could represent another 2-3% growth each. The advanced wound care market comprises diabetic foot ulcers, venous leg ulcers, pressure ulcers and complex wounds. This market is supported by a demographic tailwind as the population of the US ages, and diabetes and obesity remain epidemic. Management estimates the advanced wound care market to be at \$1.1 billion in 2021, and to grow at 7% annually to \$1.5 billion by 2026. Likewise, the addressable surgical recovery market, comprising tissue augmentation; barrier properties; and surgical closure, is expected to grow from \$0.9 billion in 2021 to \$1.3 billion in 2026, or 10% annually, driven by similar forces driving the advanced wound care opportunity. The addressable Japanese market is estimated at \$0.5 billion in 2021, growing to \$0.7 billion by 2026 with the potential to expand beyond lower extremity wounds, where MiMedx will have first-mover advantage. Management then detailed specific steps in the strategies to pursue the three growth areas.

Management then announced the expansion of MiMedx' portfolio with the 1H:22 launch of two products.

**Exhibit V - AmnioEffect and Placental Collagen Matrix<sup>7</sup>**



To conclude, MiMedx' Chief Financial Officer, Peter Carlson reported on year-to-date 2021 financial results. Net sales were up 6.4% from \$180M to \$191M, and advanced wound care/section 361 net sales jumped 15.9% from \$149M to \$173M, offsetting the decrease in sales of section 351 product that fell from \$31.7M to \$17-\$18M. Carlson explained that management expected the firm to be free cash flow neutral over the next year (2022), and free cash flow positive by the end of 2023. Over the next 12-15 months, management expects revenues to recover to

<sup>7</sup> MDXG Investor Day Presentation, December 2021

pre-Enforcement Discretion levels. Carlson revised adjusted net sales guidance, which ignores cash contributions from remaining contracts, upward to \$253M - \$258M for 2022. Further financial outlook is planned to be provided at the JP Morgan Conference during the company's presentation on Wednesday, January 12, 2022.

### **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
- Virtual Investor Day – December 2021

### **Valuation**

MiMedx' impressive presentations during its analyst day, improved knowledge regarding mechanism of action, detailed and credible plans for commercializing new and existing products and clarity on the reasons for the lack of statistical significance in the post-COVID Phase II KOA trial give us increased confidence that growth plans are achievable over the next 5 – 10 years. Annual guidance was increased, and we raise our revenue estimates for 2020 and beyond to reflect the news provided during the event. We think that MiMedx management has the experience, skill and determination to execute on plans to grow existing and new products into existing and new markets such as advanced wound care and surgical recovery. Based on our increased estimates and applying our 20x 2026 EPS and 15x 2026 EBITDA discounted to present, we raise our valuation to \$12 per share.

### **Summary**

MiMedx hosted a Virtual Investor Day on December 7<sup>th</sup> where the company discussed its KOA program, as well as commercial opportunities and strategy and offered updated financial guidance for revenues. The KOA program session, led by Dr. Robert Stein, MD, PhD, revealed more information about its mdHACM KOA program, including a root-cause analysis that revealed product degradation as a function of shelf life. Management is confident they can address the deterioration issue as they target two registrational trials to begin simultaneously in 2022. Each trial will target 400-500 patients and a BLA submission is planned for late 2025. The KOA segment also revealed p-values for all WOMAC measures of efficacy, with very strong statistical significance ( $p < 0.01$ ) at the six-month marker for the first 190 patients. Michelle Massee, MiMedx' AVP, Product development, presented preclinical research into key cellular pathways that dHACM modulates and their support for dHACM's disease-modifying potential.

Following the KOA discussion and path forward, MiMedx also detailed its commercial business growth strategy and market opportunities. The commercial strategy portion was led by Rohit Kashyap, PhD. In this session management highlighted three areas of commercial growth potential: advanced wound care, surgical recovery and international markets, namely Japan. Additionally, MiMedx announced the expansion of its product portfolio with the expected launch of two products in 1H:22, AmnioEffect and Placental Collagen Matrix. Finally, MiMedx CFO, Pete Carlson concluded by reviewing financial performance and revising revenue guidance upward to \$253M-\$258M.

MiMedx holds sufficient cash on its balance sheet to reach 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. Based on the credible details of the growth plans going forward and upward guidance, we revisit our valuation and raise our target price to \$12.00 per share.

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

## PROJECTED FINANCIALS

### MiMedx Group, Inc. - Income Statement<sup>8</sup>

MiMedx Group, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
<b>Total Revenues (\$US '000)</b>	<b>\$248,234</b>	<b>\$59,967</b>	<b>\$68,165</b>	<b>\$63,074</b>	<b>\$62,260</b>	<b>\$253,466</b>	<b>\$289,965</b>	<b>\$342,159</b>
YOY Growth	-17%	-3%	27%	-2%	-9%	2%	14%	18%
Cost of Goods Sold	\$39,330	\$9,641	\$12,760	\$10,129	\$9,962	\$42,492	\$46,394	\$54,745
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
<b>Income from operations</b>	<b>(\$45,398)</b>	<b>(\$6,852)</b>	<b>(\$410)</b>	<b>(\$1,075)</b>	<b>(\$2,794)</b>	<b>(\$11,131)</b>	<b>\$29,483</b>	<b>\$71,395</b>
Operating Margin	-18%	-11%	-1%	-2%	-4%	-4%	10%	21%
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
<b>Pre-Tax Income</b>	<b>(\$61,543)</b>	<b>(\$8,324)</b>	<b>(\$1,784)</b>	<b>(\$2,038)</b>	<b>(\$3,669)</b>	<b>(\$15,815)</b>	<b>\$25,983</b>	<b>\$67,895</b>
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%	2.2%	0.0%	0.0%
<b>Net Income</b>	<b>(\$49,284)</b>	<b>(\$8,382)</b>	<b>(\$1,779)</b>	<b>(\$2,339)</b>	<b>(\$3,669)</b>	<b>(\$16,169)</b>	<b>\$25,983</b>	<b>\$67,895</b>
Net Margin	-20%	-14%	-3%	-4%	-6%	-6%	9%	20%
<b>Reported EPS</b>	<b>(\$0.46)</b>	<b>(\$0.08)</b>	<b>(\$0.01)</b>	<b>(\$0.02)</b>	<b>(\$0.03)</b>	<b>(\$0.14)</b>	<b>\$0.18</b>	<b>\$0.46</b>
YOY Growth		70.9%	-83.8%	-88.2%	-78.6%	-69%	-232%	150%
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

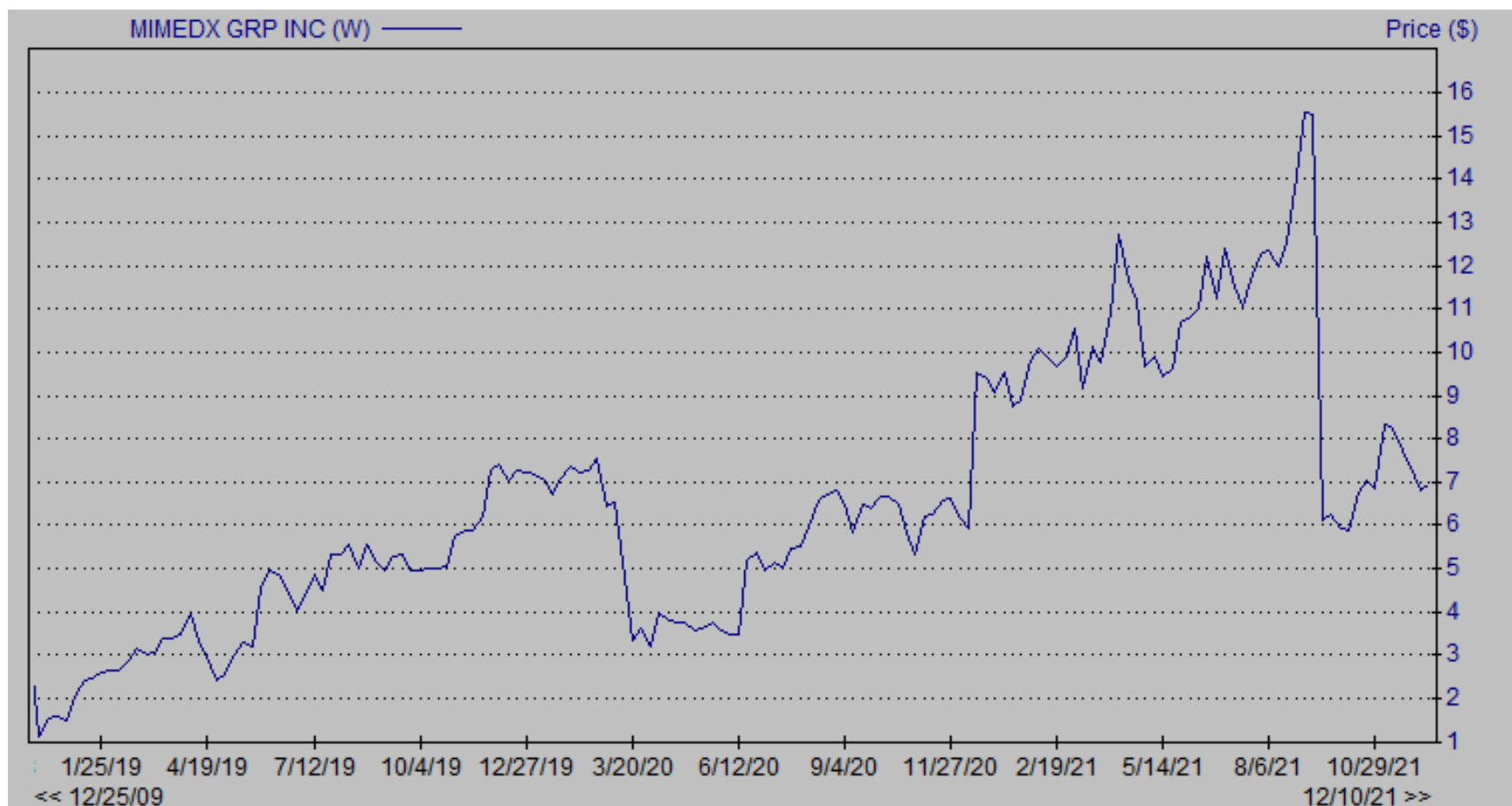
Source: Company Filing // Zacks Investment Research, Inc. Estimates

<sup>8</sup> Financial statement information presents data as originally reported.



## HISTORICAL STOCK PRICE

### MiMedx Group, Inc. – Share Price Chart<sup>9</sup>



<sup>9</sup> Source: Zacks Research System



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