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March 1, 2022
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

MiMedx Group, Inc. (MDXG - NASDAQ)

2021 Results

Based on our multiple of earnings model and a 20% discount rate, MiMedx target price is approximately $11.00 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 (2/28/2022)	$5.05
Valuation	**$11.00**

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 numerous solutions for wound & burn repair & expects to expand the portfolio yearly with new offerings. 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 in 2H:22 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	**$4.12**
One-Year Return (%)	**-45.2**
Beta	**1.96**
Average Daily Volume (sh)	**635,137**
Shares Outstanding (mil)	**139**
Market Capitalization ($mil)	**702**
Short Interest Ratio (days)	**6.35**
Institutional Ownership (%)	**60.1**
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 2021 Estimate	**N/A**
P/E using 2022 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 (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	$67.4 A	$258.6 A
2022					$266.4 E
2023					$314.4 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	$0.02 A	-$0.09 A
2022					-$0.03 E
2023					$0.31 E

*4Q:21 EPS is as calculated by our model ignoring Series B Convertible effect.

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WHAT'S NEW

2021 Financial and Operational Results

After market close on February 28, 2022, MiMedx Group, Inc. (NASDAQ: MDXG) filed Form 10-K with the SEC and issued a press release summarizing its financial and operational results for the year ended December 31, 2021. A conference call and webcast was held to communicate additional detail to analysts and investors.

MiMedx impressed us with better than expected revenues in the fourth quarter which are expected to be further enhanced by new products and international expansion in 2022. While this year is expected to begin with mid-single digit organic growth,[1] impacts from new sources are expected to drive accelerating revenue growth as the year progress and company management has guided up to a 20% year over year increase by 4Q:22. Some of the key items to watch for in 2022 include a reimbursement decision and first sales of EpiFix in Japan around mid-year, launch of new products AmnioEffect and Placental Collagen Matrix to address wounds that require thicker coverage or are difficult to reach and the start of the knee osteoarthritis (KOA) trial.

Highlights for the fourth quarter ended December 31st and to-date include:

- Two studies demonstrating potential of mdHACM in OA and tendinopathy processes - November 2021
- dHACM outperforms SoC in select Mohs defect reconstructions - November 2021
- Virtual Investor Day - December 2021
- Key strategic milestones for 2022 - January 2022
- Dismissal of putative securities class action lawsuit - January 2022
- Study demonstrating cost effectiveness of dHACM vs SoC in LEDU[2] - February 2022

Revenues and net loss for the year were $258.6 million and ($10.3) million, respectively, and net loss available to common stockholders was ($16.4) million. Net loss per share was ($0.09) and net loss per share to common stockholders, which recognizes the dividend paid to Series B convertible holders, was ($0.15). These results compare to net loss of ($0.45) and ($0.77) at the end of 2020, respectively.[3]

For the year ending December 31, 2021, compared to the same ending December 31, 2020:

- Reported revenues were $258.6 million, up 4.2% from $248.2 million. Revenue decrease in Section 351 product was more than offset by organic growth in advanced wound care offerings;
- Gross margin was 83.3% vs 84.2%, due primarily to Section 351 product write-downs that will not recur in 2022;
- SG&A was $198.4 million, up 9.6% from $181.0 million driven by full restoration to pre-COVID salaries, increase in sales force, higher travel costs, proxy contest costing ~$3.9 million, and increase in sales commissions;
- Investigation, restatement and related expenses were $3.8 million, down 93.6% from $59.5 million as expenses declined with the resolution of legal proceedings relating to former officers and directors;
- R&D expenses were $17.3 million, increasing 48.0% from $11.7 million, reflecting increases in personnel costs, driven by increases in headcount to support clinical research efforts, and restoration of full salary levels and merit increases;
- Operating income was ($5.0) million vs ($45.4) million;
- Interest expense was ($5.0) million versus ($7.9) million;
- Net loss was ($10.3) million versus ($49.3) million, or ($0.09) per share versus ($0.45) per share;
- Net loss available to common stockholders was ($16.4) million vs ($83.3) million or ($0.15) and ($0.77).

[1] This excludes the impact of Section 351 product in 2021.
[2] Lower Extremity Diabetic Ulcer
[3] 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.

As of December 31, 2021, cash stood at $87.1 million. Debt was carried on the balance sheet at $48.1 million. Cash burn for the year was ($5.5) million compared to ($34.8) million in the prior year on lower net loss, absence of loss on extinguishment of debt, and support from income taxes and accrued compensation, offset by accrued expenses. Adjusted EBITDA, as calculated by the company which adds back costs incurred related to the investigation and restatement and share based compensation, was $17.9 million which compares to prior year amount of $30.6 million. EBITDA calculated by the company and Zacks was $146,000.

Investor Day
On December 7, 2021, MiMedx held a Virtual Investor Day held via webcast which featured a number of distinguished Key Opinion Leaders (KOLs). The primary concern since the September 13th topline data report for 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. The analysis suggests 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. We summarized the detail from the event in our research report here.

Key takeaways from the Investor Day include:

- Interim result details including p-values from Phase IIb KOA study supporting registrational trials;
- Root cause analysis related to shelf life 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.

Key Strategic Milestones for 2022
On January 10, 2022, MiMedx reiterated its 2021 accomplishments and announced 2022 initiatives and guidance. With the revelation of the shelf-life issues that obscured endpoint results from MiMedx' recent Phase IIb KOA trial, the company plans to start a Phase III study in knee osteoarthritis (KOA) in 2H:22, targeting a late-2026 commercial launch. The company also aims for double-digit revenue growth in 2022 driven primarily by advancement into the surgical recovery market, launch of EpiFix in Japan in mid-2022, and launch of two new products in 1H:22, echoing initiatives presented in MiMedx' recent December 7th Investor Day. 2021 highlights included receiving regulatory approval for EpiFix in Japan, multiple peer-reviewed clinical; scientific; and economic publications, additional Investigational New Drug (IND) applications, double-digit topline sales growth, expansion of MiMedx' sales force, and Phase IIb KOA trial results.

2022 Anticipated Milestones include:

- Mid-2022 launch of EpiFix in Japan;
- Commence two Phase III clinical trials in KOA;
- Implement rigorous cGMP[4] standards throughout supply chain;
- Publish peer-reviewed publications on research and clinical studies;
- Launch new US products: AmnioEffect and Placental Collagen Matrix.

MiMedx also provided financial guidance for 2022:

- Annual revenue growth of 11%-14% in existing product portfolio;
  - 1Q:22: mid-single digit percent growth;
  - 2Q:22: high-single digit percent growth;
  - 3Q:22: mid- to high-teens percent growth;
  - 4Q:22: high-teens to twenty percent growth;
- R&D spend is expected to increase to a range of $17 - $22 million;
- Gross margin is expected to be slightly lower due to competition and product mix.

[4] Current Good Manufacturing Practice

As we published on January 20, 2022, we had a chance to catch up with MiMedx management following their issuance of updated guidance and discussions with investors at early January conferences. Based on our conversations and review of updated company materials, we adjusted our revenue, expense and earnings estimates for future periods. Estimated core 2021 revenues, which exclude Section 351 product, were expected to be from $236 to $240 million. Actual core revenues were at the top of this range at $240.0 million.

Dismissal of Putative Securities Class Action Lawsuit
On January 28, 2022, MiMedx announced the dismissal of the securities class action lawsuit brought on by the Carpenters Pension Fund of Illinois (CPFI) that claimed that MiMedx violated federal securities laws. US District Judge William Ray II, a federal judge in the Northern District of Georgia, granted MiMedx' Motion to Dismiss and ruled that he would not reconsider his decision.

Publications

Two Studies Demonstrating Potential of mdHACM in OA and Tendinopathy Processes
On November 1, 2021, MiMedx announced two studies, published in *Osteoarthritis and Cartilage Open* and *Journal of Biomedical Materials Research, Part B,* respectively.

The first study, entitled "Human amniotic membrane modulates Wnt/β-catenin and NF-κβ signaling pathways in articular chondrocytes in vitro," identified a novel mechanism of action by which mdHACM regulates degrative processes in human articular chondrocytes, the primary cell type in articular cartilage, further supporting mdHACM indication in osteoarthritis, as well as its potential for disease-modifying labeling. There are over 300 million global cases of hip and knee osteoarthritis, and the current standard of care is NSAIDs and corticosteroid injections, and ultimately joint replacement. mdHACM is hypothesized to target specific pathways in the pathophysiology of osteoarthritis. The *in vitro* model revealed two key signaling pathways that mdHACM inhibited, NF-κβ (Nuclear Factor kappa-light-chain-enhancer of activated B cells) and canonical Wnt signaling, attenuating degradation.

The second study, entitled "Dehydrated human amniotic membrane regulates tenocyte expression and angiogenesis in vitro: Implications for a therapeutic treatment of tendinopathy," examined chronicity and outcomes attributable to prolonged inflammation and hypervascularity following tendon injury, which were modeled *in vitro* to evaluate mdHACM as a treatment for tendinopathy. In this study, human tenocytes were treated with IL-1β to induce a state mimicking tendon injury, as evident by the increased expression of inflammatory and catabolic markers. Previous studies have reported that the mRNA levels of inflammatory cytokines such as IL-1β are remarkably up-regulated in injured tendons.[5] Introduction of mdHACM diminished the effects of IL-1β, including downregulation of IL-6, MCP-1, MMP-1, and MMP-3, and reversed expression of type III collagen, supporting the potential of mdHACM in the treatment of tendinopathy.

dHACM Outperforms SoC in Select Mohs Defect Reconstructions
On November 17, 2021, MiMedx announced the publication of "Mohs Defect Repair with Dehydrated Human Amnion/Chorion Membrane" in *Facial Plastic Surgery & Aesthetic Medicine*, which investigated the safety and utility of dHACM for use in Mohs micrographic surgeries (MMS). MMS aims to remove as much diseased tissue as possible while sparing as much healthy tissue as possible. Thin layers of tissue (skin) are removed and examined under the microscope until only cancer-free tissue remains. The retrospective, case-controlled study patient population (n = 286) included 143 propensity score-matched pairs undergoing MMS for a basal or squamous cell carcinoma on the face, head, neck, or dorsal hands with same-day reconstruction using either autologous tissue or dHACM placental allograft, between January 2014 and December 2018; the study demonstrated that dHACM allografts were associated with a statistically significant lower risk of infection ($p = 0.004$), poor scar cosmesis ($p < 0.0001$), scar revision ($p < 0.0001$), or reoperation ($p = 0.0007$), when compared to traditional methods of incisional repair, namely autologous tissue flaps and full-thickness skin grafts. MMS is considered the most effective technique for treating many basal and squamous cell carcinomas, the two most common types of non-melanoma skin cancer. With the incidence of NMSC increasing rapidly in people over 65, Mohs has become a common procedure to remove these cutaneous malignancies. Tumors in this population are often more invasive, requiring removal of more tissue, which increases the need for alternative tissue sources. Patients receiving dHACM were 19 times less likely to have unacceptable scarring, and 12 times less likely to become infected or require additional surgery.

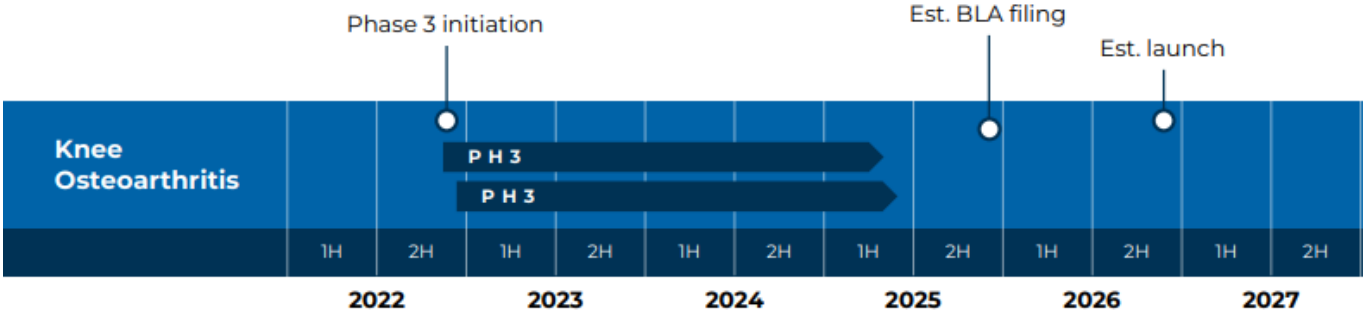
[5] Zhang, K., Asai, S., Yu, B., & Enomoto-Iwamoto, M. (2015). IL-1β irreversibly inhibits tenogenic differentiation and alters metabolism in injured tendon-derived progenitor cells in vitro. *Biochemical and biophysical research communications*, *463*(4), 667–672. https://doi.org/10.1016/j.bbrc.2015.05.122

Study Demonstrating Cost-Effectiveness of dHACM vs SoC in Lower Extremity Diabetic Ulcers
On February 16, 2022, MiMedx announced a publication in the *Journal of Wound Care* that evaluated the cost-effectiveness of dHACM versus standard of care in treating lower extremity diabetic ulcers (LEDU), including diabetic foot ulcers (DFU). The study retrospectively analyzed 10.9 million Medicare diabetes patients, 1.2 million of whom had an LEDU, and tracked outcomes including amputations and healthcare utilization. Timely use of dHACM significantly reduced long-term healthcare costs compared to standard of care and no treatment. Furthermore, LEDU episodes treated with dHACM, following parameters for use, led to statistically fewer amputations and health care utilization, including emergency visits, inpatient admissions and readmissions. It was estimated that in year one, dHACM saved $3,670 per patient and provided a QALY[6] gain of 0.013 years. Assuming a willingness to pay of $100,000 per QALY, the five-year net benefit per patient was ~$5,000. DFUs represent an annual incidence of 6%-7% in the Medicare population and 4% in the commercially insured population. For a typical million-person plan, potential savings could amount to $22 million annually.

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
  - Launch of EpiFix in Japan – Mid-2022
- Virtual Investor Day – December 2021
- Launch AmnioEffect and Placental Collagen Matrix – 1H:22
- Phase III KOA trials launch – 2H:22
  - 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
  - BLA submission – Late-2025
  - Commercial launch – Late 2026

Exhibit I – KOA Timeline[7]



[6] Quality-adjusted life years
[7] Source: MiMedx January 2022 JP Morgan Healthcare Conference Presentation

Summary

On February 28, 2022, MiMedx reported financial and operational results for calendar year 2021. Revenues and net loss for the year were a better than expected $258.6 million and ($10.3) million, respectively, and net loss available to common stockholders was ($16.4) million. Net loss per share was ($0.09) and net loss per share to common stockholders, which recognizes the dividend paid to Series B convertible holders, was ($0.15).

Highlights for 2021 and to date include readouts from multiple studies, recovery from the loss of Section 351 product, and several new avenues for growth from geographical and product expansion in 2022. MiMedx also was granted its motion to dismiss a lawsuit brought upon the company by the Carpenters Pension Fund of Illinois. MiMedx is also expecting to start its KOA trial in the second half which, if successful, could be a major value driver if approved by the FDA. We maintain our valuation to $11 per share.

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement[8]

MiMedx Group, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 A	2021 A	2022 E	2023 E
Total Revenues ($US '000)	**$248,234**	**$59,967**	**$68,165**	**$63,074**	**$67,409**	**$258,615**	**$267,093**	**$315,170**
YOY Growth	-17%	-3%	27%	-2%	-2%	4%	3%	18%
Cost of Goods Sold	$39,330	$9,641	$12,760	$10,129	$10,753	$43,283	$52,083	$50,427
Product Gross Margin	84.2%	83.9%	81.3%	83.9%	84.0%	83.3%	80.5%	84.0%
Selling, general & administrative	$181,022	$45,404	$53,599	$46,289	$53,068	$198,360	$193,000	$194,930
Investigation, restatement etc.	$59,465	$7,196	($2,062)	$3,170	($4,513)	$3,791	$0	$0
Research & development	$11,715	$4,339	$4,063	$4,368	$4,575	$17,345	$22,000	$20,000
Amortization of intangible assets	$1,073	$239	$215	$193	$173	$820	$1,088	$1,088
Impairment of intangible assets	$1,027	$0	$0	$0	$53	$53	$55	$0
Income from operations	($45,398)	($6,852)	($410)	($1,075)	$3,300	($5,037)	($1,133)	$48,725
Operating Margin	-18%	-11%	-1%	-2%	5%	-2%	0%	15%
Interest income, net	($7,941)	($1,472)	($1,371)	($963)	($1,174)	($4,980)	($3,500)	($3,500)
Other income, net	($8,204)	$0	($3)	$0	($20)	($23)	$0	$0
Pre-Tax Income	($61,543)	($8,324)	($1,784)	($2,038)	$2,106	($10,040)	($4,633)	$45,225
Provision for Income Tax	$12,259	($58)	$5	($301)	$108	($246)	$0	$0
Tax Rate	-19.9%	0.0%	0.0%	0.0%	0.0%	2.5%	0.0%	0.0%
Net Income	**($49,284)**	**($8,382)**	**($1,779)**	**($2,339)**	**$2,214**	**($10,286)**	**($4,633)**	**$45,225**
Net Margin	-20%	-14%	-3%	-4%	3%	-4%	-2%	14%
Reported EPS	**($0.46)**	**($0.08)**	**($0.01)**	**($0.02)**	**$0.02**	**($0.09)**	**($0.03)**	**$0.31**
YOY Growth		70.9%	-83.8%	-88.2%	-112.8%	-80%	-66%	-1052%
Basic Shares Outstanding	108,257	109,401	110,277	110,717	110,997	110,353	120,243	135,258
Fully Diluted Shares	108,257	141,924	140,277	141,375	113,184	140,334	144,500	148,193

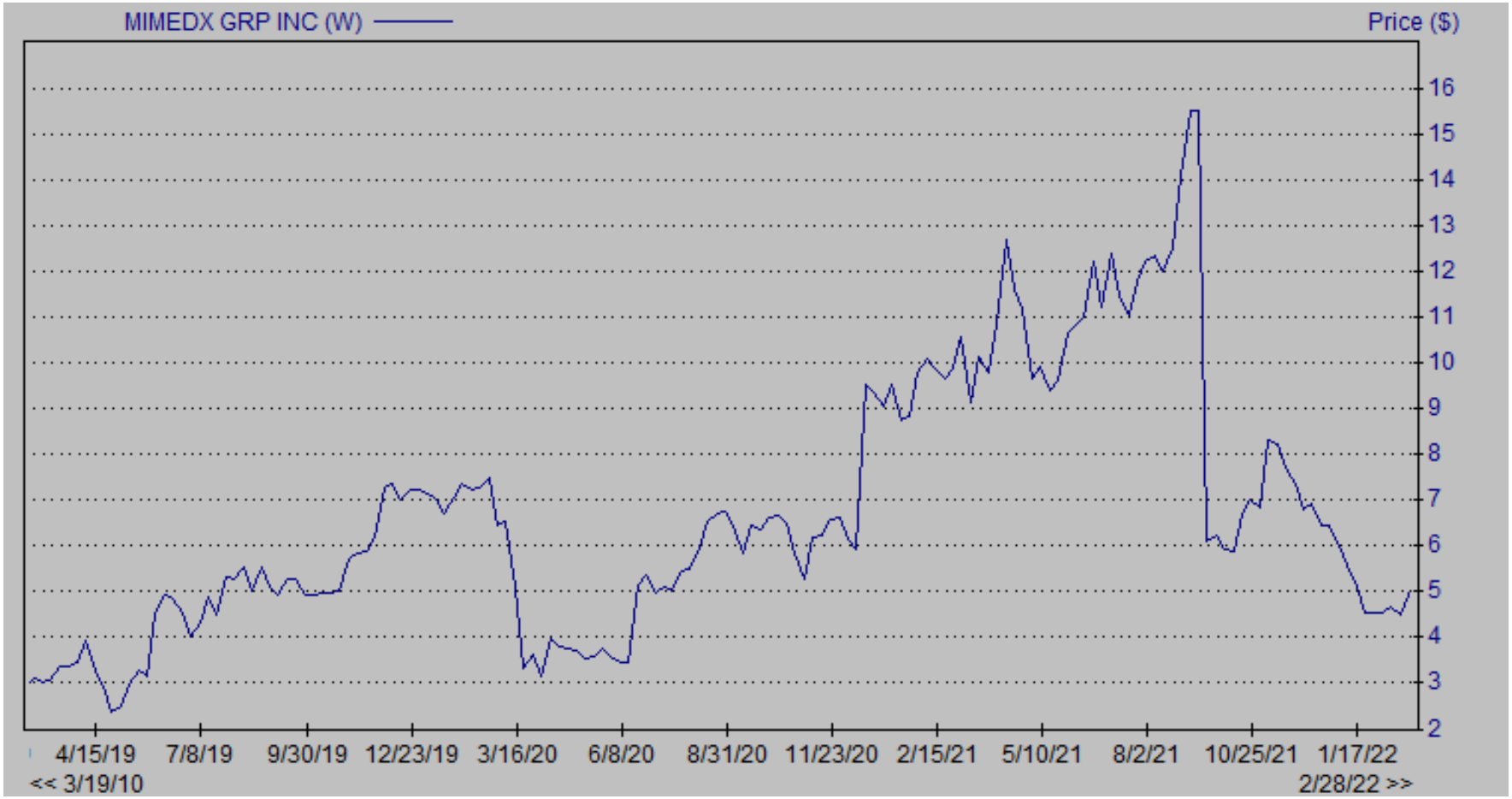
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[8] Financial statement information presents data as originally reported.

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HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[9]



[9] Source: Zacks Research System

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