Zacks Small-Cap Research

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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)

2022 Financial 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 (2/28/2023)	$4.81
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 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. A Phase III clinical trial has begunfor AmnioFix injectable in KOA and other indications based on products subject to enforcement discretion.

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	**$5.28**
52-Week Low	**$2.43**
One-Year Return (%)	**-4.8**
Beta	**1.8**
Average Daily Volume (sh)	**549,291**
Shares Outstanding (mil)	**144**
Market Capitalization ($mil)	**691**
Short Interest Ratio (days)	**5.0**
Institutional Ownership (%)	**65.6**
Insider Ownership (%)	**4.1**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**241**
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)
2021	$60.0 A	$68.2 A	$63.1 A	$67.4 A	$258.6 A
2022	$58.9 A	$66.9 A	$67.7 A	$74.4 A	$267.8 A
2023					$294.6 E
2024					$335.9 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.08 A	-$0.01 A	-$0.02 A	$0.02 A	-$0.09 A
2022	-$0.09 A	-$0.10 A	-$0.06 A	$0.00 A	-$0.21 A
2023					$0.02 E
2024					$0.21 E

*EPS is as calculated by our model ignoring Series B Convertible effect.

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WHAT'S NEW

2023 Updates

MiMedx Group, Inc. (NASDAQ: MDXG) reported full-year revenues of $267.8 million, at the high end of recent guidance. Loss from operations was ($25.0) million, negatively impacted by higher-than-expected Investigation and Restatement costs that were not fully offset by SG&A and R&D expenses which came in lower than our estimates. Fourth quarter and full year 2022 results were reported in a press release, filing of Form 10-K and a conference call with management which provided an opportunity for analyst Q&A.

The knee osteoarthritis (KOA) trial has begun and is now screening subjects. Other news since the third quarter report includes an agreement with Turn Therapeutics that provides MiMedx access to Turn's PermaFusion antimicrobial platform. New executive officer Ricci Whitlow was added after the beginning of the year as Chief Operating Officer and the commercial launch of EPIFIX was officially started with an exclusive distribution agreement with Gunze Medical Limited. The company also appointed permanent CEO Joseph H. Capper at the end of January to take the reins from interim CEO Todd Newton, who will remain on the Board.

Revenues and net loss for 2022 were $267.8 million and ($30.2) million with net loss available to common stockholders of ($36.8) million. The difference between the two measures is attributable to the dividend on the Series B convertible stock. Net loss per share was ($0.21) and for common stockholders ($0.33). These results compare to revenues and net loss of $258.6 million and ($0.09) generated in 2021.[1]

For the year ending December 31, 2022, compared to the one ending December 31, 2021:

- Reported revenues were $267.8 million, up 4% from $258.61 million. Revenue increased on expanding sales from growth in advanced wound care products and surgical recovery. New products, including Amnioeffect and Axiofill provided further gains;
- Gross margin declined by 130 basis points to 82.0% from 83.3% on negative impacts from production variances largely due to lower product production levels;
- SG&A was $208.8 million, up 5.3% from $198.4 million reflecting higher travel expenses, greater sales commissions, more bad debt and a bump in severance costs partially offset by a decrease in share-based compensation expense;
- Investigation, restatement and related expenses were $12.2 million, up from $3.8 million;
- R&D expenses were $22.8 million, increasing 32% from $17.3 million, related to higher personnel costs and clinical trial-related expenses to support clinical research efforts, primarily connected to the commercial and late-stage pipelines;
- Operating loss was ($25.0) million vs ($5.0) million;
- Interest expense was ($5.0) million versus ($5.0) million;
- Net loss was ($30.2) million versus ($10.3) million, or ($0.21) per share versus ($0.09) per share.

As of December 31, 2022, cash stood at $66.0 million, compared to $87.1 million at year end 2021 on cash burn of ($20.6) million. Debt was carried on the balance sheet at $48.6 million. 2021 cash flows were pressured by increases in working capital and prepaid expenses. Adjusted EBITDA for 2022, as calculated by the company which adds back costs incurred related to the investigation and restatement and share based compensation, was ($3.9) million which compares to prior year contribution of $17.9 million. EBITDA calculated by the company and Zacks was ($20.9) million and $146,000 for the 2022 and 2021 twelve-month periods respectively.

Turn Therapeutics

In early December 2022, MiMedx announced an agreement with Turn Therapeutics to provide the benefits of its antimicrobial technology, PermaFusion, to support the development of new wound and surgical recovery products. This will allow faster development of amniotic tissue and particulate products with antimicrobial features. Turn has several FDA cleared products and one 510k submitted for an antimicrobial collagen matrix which is important as it would be the first antimicrobial particulate product cleared if the FDA grants marketing approval.

[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.

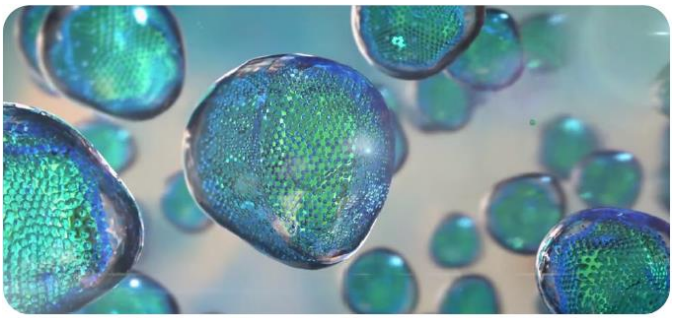
Exhibit I – Products and Pipeline[2]

Product Name	Stage
Hexagen Antimicrobial	FDA Cleared
Xeal Antimicrobial Wound Dressing	FDA Cleared
AtopX Eczema Management Tool	FDA Cleared
FleX Antimicrobial Collagen Matrix	510k Submitted
Xeal Non-Stick Antimicrobial Gauze	In Development
X-Fill Hemostat	In Development

To gain access to the partnership, MiMedx provided a $1 million upfront payment. There are also other milestones related to approval and sales targets that provide an inexpensive way to access this technology that has already been recognized by the FDA. A low single digit royalty will also be owed on sales that use the technology.

Turn's PermaFusion technology is petrolatum-based, liquid-in-oil suspension technology that forms nanodroplets without binding agents or emulsifiers and includes a process to coat materials with antimicrobial-infused petrolatum. Turn's intellectual property protection includes patents covering manufacturing processes related to mixing and coating. MiMedx will be able to employ this technology in the creation of a number of new antimicrobial biologic products for the wound, burn and surgical markets.

Exhibit II – Turn Therapeutics[3]



TURN THERAPEUTICS

Commercial Launch of Epifix in Japan

Reimbursement approval for Epifix was granted for Japan in late 2022 as shared in a September 12th release. Commercial launch was announced on January 4th, 2023 with an exclusive distribution agreement with Gunze Medical Limited and first sales have taken place. Gunze distributes a wide selection of bioabsorbable devices, medical products and materials including artificial skin brands Pelnac and Pelnac Gplus. While the company was founded and headquartered in Japan, it also has operations in Europe, Asia and the Americas. Gunze offers a team of 90 sales representatives across Japan and strong existing relationships with providers. The partner will further advance the physician education regarding Epifix and support key opinion leader (KOL) engagement.

[2] Source: Analyst work using disclosures from Turn Therapeutics' website accessed January 2023.
[3] Source: MiMedx January 2023 Corporate Presentation

The Epifix launch team has collaborated with other entities such as local physician societies including the Japanese Society for Foot Care and Podiatric Medicine and 20 KOLs throughout the country to increase physician awareness. Over 250 doctors have been trained on the product and several have already treated patients using Epifix.

Now that Epifix is available in Japan, MiMedx has access to an estimated $500 million market and 400,000 patients in the hard to heal wound space for the treatment of refractory diabetic and venous ulcers. Epifix is the only amniotic tissue product approved in Japan and an important stepping off point for further product penetration. The product is eligible for reimbursement from the Japanese Social Healthcare System. Pricing for the product was set at 35,100 Yen/cm^2 or approximately $245 per square centimeter using recent exchange rates. Further milestones required prior to sale include completing distributor agreements, training, gaining local patient experience and building market awareness. As of the date of the press release, over 250 physicians have been trained on the use of Epifix with further penetration expected. We expect it to take three to four years for Epifix to reach its terminal penetration rate.

Joseph H. Capper Appointed as Chief Executive Officer

The Board of Directors appointed Joseph H. Capper as Chief Executive Officer as memorialized in a press release on January 30, 2023. Mr. Capper replaces interim CEO Todd Newton who assumed the role in early September 2022. Previously, he served as CEO of several organizations in the health care field including BioTelemetry, Home Diagnostics and CCS Medical. He also has big pharma experience with Bayer AG, where he held multiple leadership positions and functioned as the National Sales Director of the Diabetic Products Division. He also served as a Naval Aviator and congressional liaison during his time as a naval officer. His academic background includes an undergraduate degree in Accounting from West Chester University and an MBA in International Finance from George Washington University.

Ricci S. Whitlow Appointed as Chief Operating Officer

On January 3, 2023, MiMedx announced that Ricci S. Whitlow had been appointed as Chief Operating Officer (COO) to lead the company's manufacturing, supply chain, procurement, quality, and regulatory functions. She had previously held the role of President at Catalent where she led the Clinical Supply Services division. Other companies listed on Ms. Whitlow's resume include Optinose, LifeCell, Kinetic Concepts and Johnson & Johnson. She earned a Bachelor of Science in Industrial Engineering from Texas A&M University and a Masters of Business Administration from New York University.

CMS Proposal for Skin Substitutes

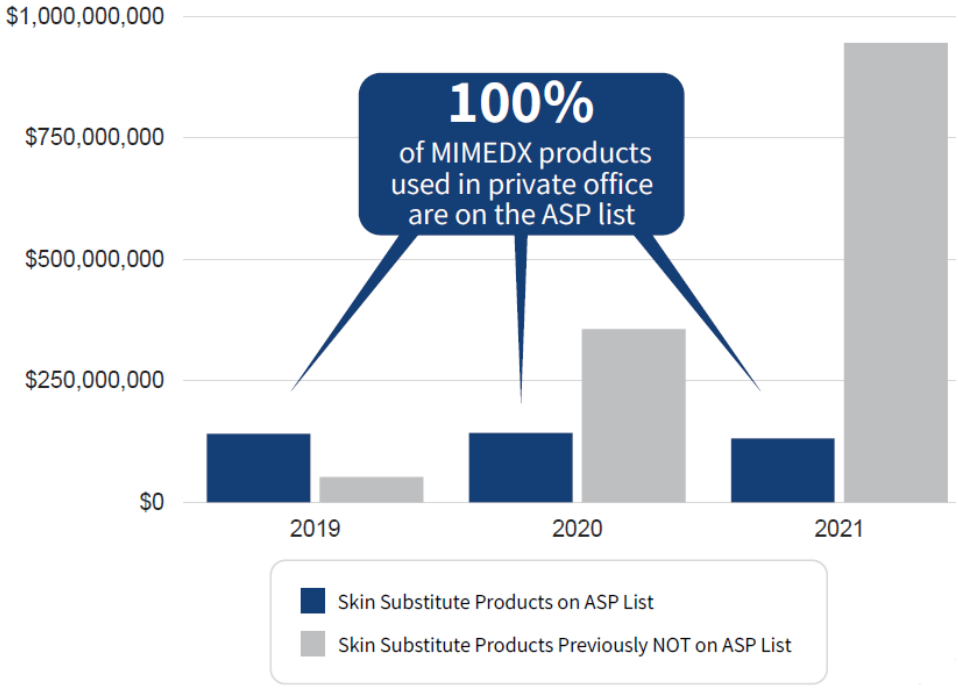
Roughly 21% of MiMedx' business is comprised of private office wound care which is affected by Center for Medicare and Medicaid Services (CMS) pricing and bundling practices.[4] Of these sales, over 90% is related to Epifix and the remainder from Epicord. In the last few years, skin substitute products that were previously not listed on the Average Sales Price (ASP) list have led to a dramatice increase in Medicare expenditure, that according to input from the team in the field, were driven by increased use of financial incentives. The rise is spending has led to efforts by Medicare to reduce costs and transition all skin substitutes to the ASP list. The agency is now in the process of receiving feedback from stakeholders and is expected to come up with refinements that reduce unnecessary spending in this category. MiMedx has taken steps to reduce the risk of revenue loss related to the potential changes and has encouraged CMS to adopt the following:

- Advocate for fair competition and publish all skin substitutes on the ASP list
- Introduce a new standard of clinical evidence as a prerequisitie to coverage
- Follow clinical standards and allow sufficient applications to support proper wound care

MiMedx believes that based on existing information, the company has mitigated much of the controllable risk to products on the ASP list. This confidence is supported by the receipt in December of the Epifix Tissue Reference Group (TRG) letter and the body of evidence for the use of MiMedxproducts in clinical literature.

[4] This was revised lower from about 30% in MiMedx original discussion of the issue as not all private physician business is reimbursed by CMS-regulated pricing.

Exhibit III – Skin Substitute Products – Medicare Allowed Charges[5]



Background
In recent periods, competitors with lesser quality or more basic products present a financial incentive that has shifted demand away from MiMedx' skin substitute products, potentially to the detriment of the patient. CMS presented draft guidance that failed to address this issue and has since realized that the issue is more complex than initially thought. CMS' proposal was to transition private office reimbursement to a bundled pricing scheme in 2024. It may consolidate into a single bundle rather than a high and low cost bundle which could pose pricing pressure on MiMedx' skin substitute as lower cost and less effective alternatives (such as simple dressings like gauze) may be used instead. As a result, the agency held a meeting in January 2023 to further understand the impact of terminology and payment policies on product use.

On November 1st CMS proposed calendar year 2023 payments for products and services that fall under its aegis. The agency has finalized a policy to assign any synthetic skin substitute that is described by the Healthcare Common Procedure Coding System (HCPCS) code C1849 to fall into the high-cost skin substitute group. For skin substitutes, CMS announced that it has not finalized its proposal to change the terminology of skin substitutes and desires additional interaction with stakeholders prior to doing so. The proposal is considering the elimination of HCPCS code C1849, which is used for synthetic skin substitutes; however this may not be in the best interest of patients as it does not provide sufficient incentive and guidance to use the correct skin substitute when appropriate. A Town Hall meeting was held with stakeholders in late January with participants voicing a desire for average selling price (ASP) + 6%, which is the standard in the industry for reimbursing pharmaceuticals. A CMS ruling on the matter is expected in the fall.

Launch of Knee Osteoarthritis Trial

MiMedx has launched its 470-subject Phase IIb knee osteoarthritis (KOA) trial and is now screening patients. The study's co-primary endpoints will be the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index pain and function scores. Three arms will be divided among a 40 mg dose of dehydrated human amnion/chorion membrane (dHACM), a 100 mg dose and saline placebo. Endpoints will be measured at six months and again at twelve months. In January the company modified the CRO agreement with Nordic in order to reflect additional elements required in conducting the trial. The change modified the scope of Nordic's responsibilities shifting some activities to other vendors to be administered by Nordic and other activities to MiMedx. The changes primarily related to areas of patient recruitment and screening and statistical analysis.

[5] Source: MiMedx January 2023 Corporate Presentation

Company Milestones

- Limited launch of AmnioEffect – June 2022
- Nordic Biosciences selected as CRO – June 2022
- Formation of Regenerative Medicine Scientific Advisory Board – July 2022
- CEO Transition – September 2022
- Full launch of AmnioEffect and AxioFill – September 2022
- Launch of EpiFix in Japan – September 2022
- Permanent CEO Joseph Capper appointed – January 2023
- Fourth Quarter and Full Year 2022 Financial and Operational Results – March 1, 2023
- Phase III KOA trials launch – February 2023
    - First patient enrolled – 1Q:23
    - BLA submission – Late 2025
    - Commercial launch – Late 2026
- Acceleration in Epifix commercialization efforts in Japan – 2023

Summary

MiMedx reported full year 2022 financial results posting a 4% increase in revenues and a net loss of ($0.21) per share. While the company was able to limit increases in expenses, they did outpace topline growth that was hampered by difficult comparisons early in the year related to the end of enforcement discretion in 2021. Investigation and restatement costs continued to burden the company and were higher than we had expected. Despite the difficulties, we continue to forecast double digit growth in the topline and expense leverage in 2023.

Over the last several months the company has been busy shuffling the management team and has added a new CEO and COO. Of significant importance for long term growth, the KOA trial has started and will be the first of two studies conducted investigating the benefits of MiMedx' micronized dehydrated human amnion/chorion membrane (mDHACM). An agreement with Turn Therapeutics will allow new products with antimicrobial features to be available and contribute new products to the portfolio. The extended effort to launch the first product in Japan has now begun to generate sales to physicians and providers. Epifix commercialization and training efforts by partner Gunze are underway and we expect to see a contribution to growth from the product in Japan in 2023. Reimbursement changes are a constant source of uncertainty with recent moves by CMS to stem the rising costs of skin substitutes. To respond to CMS' proposal, management has provided input via the agency's Town Hall forum and taken steps to minimize risk of revenue loss.

New products, new geographies and expansion of surgical recovery sales are expected to drive continued revenue expansion in 2023. Looking ahead, we expect to see MiMedx' new revenue streams driving strong growth in 2023 with additional efforts to improve margins. We maintain our valuation of $10 per share.

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement[6]

MiMedx Group, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ($US '000)	**$258,615**	**$58,894**	**$66,883**	**$67,689**	**$74,375**	**$267,841**	**$294,625**	**$335,873**
YOY Growth	4%	-2%	-2%	7%	10%	4%	10%	14%
Cost of Goods Sold	$43,283	$9,936	$11,823	$12,188	$14,369	$48,316	$47,140	$53,740
Product Gross Margin	83.3%	83.1%	82.3%	82.0%	80.8%	82.0%	84.0%	84.0%
Selling, general & administrative	$198,360	$49,570	$55,793	$53,475	$49,951	$208,789	$210,877	$213,513
Investigation, restatement etc.	$3,791	$2,552	$3,218	$3,001	$3,406	$12,177	$5,000	$0
Research & development	$17,345	$5,964	$5,512	$5,953	$5,400	$22,829	$23,500	$22,000
Amortization of intangible assets	$820	$172	$173	$175	$182	$701	$688	$688
Impairment of intangible assets	$53	$0	$0	$0	$0	$0	$0	$0
Income from operations	($5,037)	($9,300)	($9,636)	($7,103)	$1,067	($24,971)	$7,420	$45,932
Operating Margin	-2%	-16%	-14%	-10%	1%	-9%	3%	14%
Interest income, net	($4,980)	($1,126)	($1,170)	($1,270)	($1,451)	($5,016)	($5,000)	($5,000)
Other income, net	($23)	($0)	($0)	($0)	($2)	($4)	$0	$0
Pre-Tax Income	($10,040)	($10,426)	($10,806)	($8,373)	($386)	($29,991)	$2,420	$40,932
Provision for Income Tax	($246)	$63	($62)	($53)	($29)	($206)	$0	($9,414)
Tax Rate	2.5%	0.0%	0.0%	0.0%	0.0%	0.7%	0.0%	23.0%
Net Income	**($10,286)**	**($10,489)**	**($10,868)**	**($8,426)**	**($415)**	**($30,197)**	**$2,420**	**$31,518**
Net Margin	-4%	-18%	-16%	-12%	-1%	-11%	1%	9%
Reported EPS	**($0.09)**	**($0.09)**	**($0.10)**	**($0.06)**	**($0.00)**	**($0.21)**	**$0.02**	**$0.21**
YOY Growth	-80%	22.7%	496.9%	178.8%	-114.8%	127%	-108%	1163%
Basic Shares Outstanding	110,353	111,616	112,868	113,448	113,676	112,909	132,563	152,000
Fully Diluted Shares	140,334	141,076	142,490	143,048	143,236	142,469	147,363	152,000

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

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

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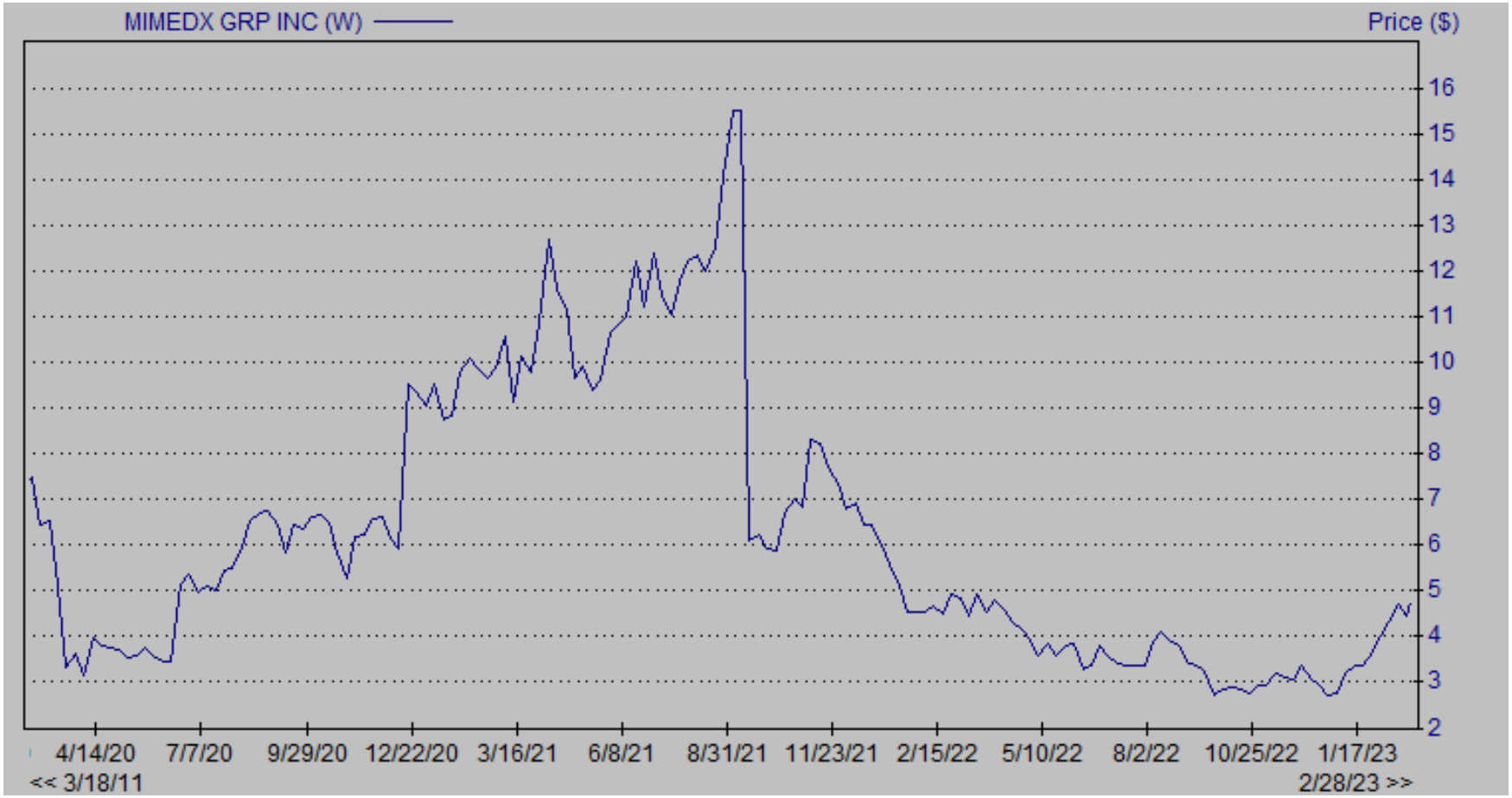
HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[7]



[7] Source: Zacks Research System

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