Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
May 1, 2024
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MiMedx Group, Inc. (MDXG: NASDAQ)

MDXG: MACs Give Credit for Efficacy

We use a multiple of earnings and a multiple of EBITDA methodology to generate our target price for MiMedx. We apply a 20x multiple of earnings to 2026 EPS, a 15x multiple to 2026 EBITDA and discount a blend of the two approaches to generate our valuation.

Current Price (4/30/2024)	$6.16
Valuation	**$13.00**

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.

MiMedx recently announced a restructuring that eliminated major development programs and closed the regenerative medicine R&D segment. The change is expected to support stronger operating margins and improve use of capital. We expect MiMedx to turn to acquisitions and partnerships as a source of new revenues and markets.

We forecast continued growth in commercialized products and success in the development pipeline that will drive topline increases. 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	**$9.27**
52-Week Low	**$4.47**
One-Year Return (%)	**60.8**
Beta	**1.4**
Average Daily Volume (sh)	**840,765**
Shares Outstanding (mil)	**148**
Market Capitalization ($mil)	**912**
Short Interest Ratio (days)	**6.2**
Institutional Ownership (%)	**61.2**
Insider Ownership (%)	**2.2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**1.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**12.6**
P/E using 2024 Estimate	**16.6**
P/E using 2025 Estimate	**9.8**
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)
2023	$71.7 A	$81.3 A	$81.7 A	$86.8 A	$321.5 A
2024	$84.7 A	$89.6 E	$92.3 E	$97.3 E	$364.0 E
2025					$425.8 E
2026					$521.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.03 A	$0.01 A	$0.07 A	$0.35 A	$0.44 A
2024	$0.06 A	$0.09 E	$0.10 E	$0.11 E	$0.36 E
2025					$0.63 E
2026					$1.04 E

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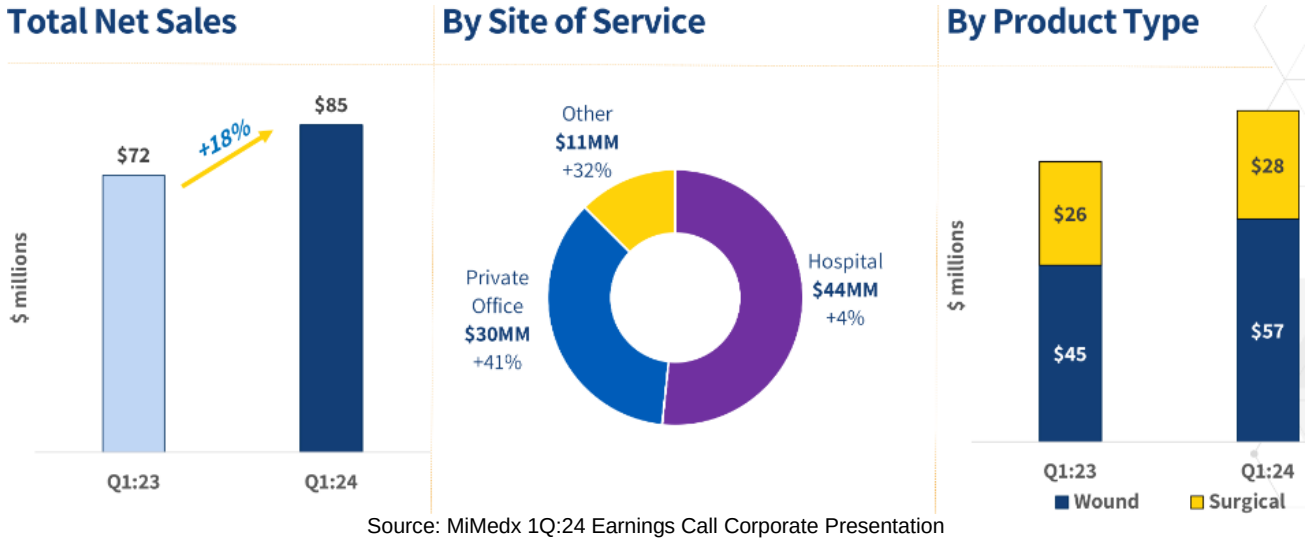
WHAT'S NEW

1Q:24 Financial and Operational Summary

MiMedx Group, Inc. (NASDAQ: MDXG) reported first quarter 2024 revenues of $84.7 million, representing an 18% year over year growth rate, surpassing our $79.0 million estimate. Pre-tax income was $11.4 million, benefiting from improved gross margin and lower research and development costs. Management maintained guidance for the year despite the strong first quarter revenue beat. Contributions from new products launched in previous years are making a material impact and the opportunity for the xenograft product from the Regenity partnership should support revenue trends in the second half of the year. The adjusted EBITDA margin was 22% of net sales in 1Q:24 and $19 million. It is expected to persist above 20% in 2024. Based on the better-than-expected revenue trends to date, we raise our valuation to $13 per share.

Exhibit I – First Quarter 2024 Net Sales



Source: MiMedx 1Q:24 Earnings Call Corporate Presentation

During the earnings call, MiMedx discussed two factors that may impact revenue on the periphery. The previously disclosed FDA letter disputing Axiofill and the Medicare Administrative Contractor (MAC) Local Coverage Determinations (LCDs). MiMedx has gone to court to support Axiofill arguing that the product has not received the same treatment as other similar products. This effort is expected to cost less than $1 million and take a year to resolve. In the meantime, Axiofill will continue to be sold. The MAC LCDs dramatically reduce the number of reimbursable skin substitutes but include two of MiMedx' products on the list due to evidentiary support.

First quarter stronger than expected results create a higher base for future revenue growth. We also increase research and development expenditure to reflect updated guidance and anticipated studies for Epieffect. The net result is a modest increase in our valuation to $13.00 per share.

Financial Results

1Q:24 results were reported in a press release, filing of Form 10-Q and a conference call with management which provided an opportunity for analyst Q&A after market close on April 30, 2024.

For the quarter ending March 31, 2023, compared to the same prior year period:

- Reported revenues were $84.7 million, up 18% from $71.7 million. All three customer segments were up year over year with private office adding the most in percent and dollar terms, rising 41%. By product category, Wound surged 26% while Surgical grew a modest 4%. Management noted that expanding contributions from Amnioeffect and Axiofill helped support the increase. New products were also important for the better year over year numbers. Sales more than doubled in Japan, however, this was off of a small base.
- Gross margin continued to impress and reached a multi-year high of 84.7%, 200 basis points over the prior year. Product mix and increased throughput efficiencies drove the increase;

- SG&A was $55.1 million, rising 5.5% from $52.3 million reflecting higher commissions to and a larger proportion of sales through sales agents;
- R&D expenses were $2.8 million, decreasing 56% from $6.5 million. Prior year R&D included costs related to the Regenerative Medicine segment;
- Other expenses related to amortization, investigation and impairment totaled $554,000, substantially below the $3.9 million in the prior period. Much lower investigation expenses were slightly offset by the recognition of impairment expense;
- Interest expense was ($1.7) million versus ($1.6) million with a number of factors including the loss on extinguishment of debt related to the Hayfin loan and lower interest from the Citizen's Credit facility and lower debt contributed to the change;
- Income tax expense of ($2.3) million was recognized vs. an expense of ($51,000) reflecting a tax rate of 20.6%. The rate was favorably impacted by the vesting of restricted stock units;
- Net income from continuing operations was $9.1 million versus a loss of ($5.0) million, or $0.06 per share versus ($0.03) per share.

As of March 31, 2024, cash stood at $48.5 million, compared to $82.0 million at year end 2023 on free cash flow of $5.0 million reduced by repayment of debt. A build in accounts receivable and inventory as well as a reduction in accrued compensation explained the majority of the difference between net income and free cash flow. Debt was carried on the balance sheet at $19.5 million.

Local Coverage Determinations

On April 25th, all seven Medicare Administrative Contractors (MACs) proposed new rules for reimbursement of skin substitutes in new local coverage determinations (LCDs). The referenced products are intended for diabetic foot and venous leg ulcers in the Medicare population. The announcement follows last year's review of reimbursement rules for skin substitutes that received pushback from stakeholders. Last week's statement initially identifies fifteen products eligible for coverage based on the strength of peer-reviewed, published evidence supporting their use. Other proposed changes limit the number of skin substitute graft applications to four, with exceptions allowed only in exceptional cases. A comment period has opened which will allow public input until early June. We anticipate finalization sometime in the second half of the year.

Two of MiMedx' products are included on the list: Epifix and Epicord. Epieffect was categorized as "no literature identified", but the company has planned clinical trials that will be conducted to provide evidentiary support. We expect the net impact of the proposed change to be a positive for MiMedx in the long term even without Epieffect. While short-term adjustments may lead to providers consuming inventories of non-covered products to the exclusion of others, over the longer term, the reduction in the number of products that may be reimbursed should substantially increase MiMedx' product market share.

Citizens Credit Agreement

On January 19th, 2024, MiMedx entered into a Credit Agreement with Citizens Bank which provides credit facilities of up to $95 million. This consists of a $75 million senior secured revolving credit facility and a $20 million senior secured term loan facility. The company borrowed $30 million under the revolving credit facility and $20 million under the term loan facility to repay the Hayfin loan of $50 million. On February 27th, MiMedx repaid $30 million of the revolving credit facility. At the end of 1Q:24, the loan was carried on the balance sheet at $19 million.

Capital Structure

Following the conversion of its Series B Convertible Preferred Stock at the end of 2023, MiMedx announced new credit facilities that are expected to reduce interest costs and provide capital which may be deployed in merger and acquisition activity. As we have noted in other channels, transaction activity in the wound care space is alive and well.[1] With anticipated free cash flow this year and access to additional financing, we think that MiMedx is on the hunt. A January 22nd press release highlighted the details of a refinancing that obtained new senior secured credit facilities of $95 million that are due January 2029. The arrangement consists of a $75 million revolving credit facility and a $20 million term loan facility. A syndicate of banks including Citizens and Bank of America participated in the

[1] Three transactions of note took place in the last year with Spectral AI combining into a SPAC, LifeNet Health buying Bioventus' wound care business and PMD Solutions snagging Promore Pharma.

funding. As of the date of the release, MiMedx had drawn $20 million in the term loan and $30 million in revolving loans, using the proceeds to repay the Hayfin Capital debt which was set to mature in June 2024.

Axiofill Letter

Last December, MiMedx issued a press release announcing that the FDA had issued a warning letter related to the classification of Axiofill as a Section 361 product. The warning letter did not relate to any other MiMedx products and was not related to product safety or adverse events. Axiofill generated less than 5% of total net sales in 2023 and there was no impact on 2023 revenues. Axiofill is used to replace or supplement damaged or inadequate integumental tissue and is derived from human placental disc extracellular matrix.

Prior to the issuance of the letter, MiMedx was actively engaged with the FDA through the Request for Designation (RFD) process. The RFD allows companies to determine the regulatory pathway for their products in consultation with the FDA. Based on our understanding, the Warning Letter will have no effect on sales until a final disposition has been made through the RFD which could take some time. Following the letter, MiMedx gathered additional details regarding the RFD and submitted the compiled data to the agency. The FDA had 60 days to make a final determination and provided a response in late March. The FDA determined that Axiofill does not qualify for classification as a Human Cell, Tissue or Cellular or Tissue-based Product (HCT/P) under Section 361 of the Public Health Service Act (PHSA). This was a final decision by the FDA, and in response, MiMedx will take steps to assert its position in court.

Exhibit II – MiMedx Portfolio Constituents



MiMedx February 2024 Corporate Presentation

The company has filed suit in the U.S. District Court for the Northern District of Georgia to overturn the FDA's decision. MiMedx feels that the agency is treating similar products differently. One human derived particulate product is considered a Section 361 product, and another was approved using the 510(k) pathway which is used for medical devices. In a previous update we discussed the Section 361 classified product, Interfyl, a connective tissue matrix. It is a placental-derived, allogeneic, decellularized, dehydrated particulate similar in manufacture and use to Axiofill.

- Section 361 Product
  - Defined as medical devices or products that do not require FDA approval
  - For human cells, tissues, and cellular and tissue-based products (HCT/Ps), the FDA evaluates whether the HCT/P is minimally manipulated to determine if it qualifies for Section 361
  - Product must be minimally manipulated undergoing processing that does not alter the original relevant characteristics of the HCT/P relating to its utility for reconstruction, repair or replacement
  - If the HCT/P is more than minimally manipulated, meaning there is a change to the biological characteristics or function, then it would require a higher level of premarket review such as a Biologics License Application (BLA)
- Section 351 Product
  - Must clear the BLA process and be expressly approved by the FDA before marketing
  - Product must be considered more than minimally manipulated

We made a minor reduction to our estimates following the December press release that assumed sales from Axiofill would taper off by year end. MiMedx has been finding alternate products to meet the needs of Axiofill users and may substitute other products in its portfolio to address surgical recovery and has also announced new arrangements to sell xenograft products which should contribute to topline. The company will be able to continue sales of Axiofill until it has exhausted its options which we anticipate will take the majority of 2024. Furthermore, MiMedx has maintained its financial guidance provided with 4Q:23 earnings. At this point, we do not expect further negative revisions related to Axiofill.

TELA Bio Arrangement for Regenity Biosciences' Xenograft Product

In an effort to mitigate the impact of a potential disruption related to Axiofill and to expand its offerings into xenografts, MiMedx has negotiated rights to commercialize a 510(k) cleared, bovine-derived collagen matrix particulate. The product is indicated for the management of exudating wounds. MiMedx has obtained exclusive rights to assume TELA Bio's rights to its manufacturing and supply agreement with Regenity Biosciences. The partnership with Regenity will allow MiMedx to augment its placental-derived product portfolio with xenografts and synthetic skin substitutes in order to expand its customer base. MiMedx anticipates that this will improve its competitive position in the Wound and Surgical markets.
The agreement will immediately add a 510(k)-cleared, bovine-derived, collagen matrix product to MiMedx' portfolio indicated for the management of moderately to heavily exudating wounds and to control minor bleeding. The collagen in this product serves as a dressing that allows for cell adhesion and migration into the wound site and supports wound healing. It is provided in particulate form allowing it to be molded or packed to conform to various wound types such as pressure ulcers, venous stasis ulcers, diabetic ulcers, acute wounds, for example trauma and surgical wounds, and partial-thickness burns.

Under the terms of the agreement with TELA Bio, MiMedx made an initial $5.0 million payment and is obligated to make additional future payments ranging from a minimum of $3.0 million and a maximum of $7.0 million based on net sales of the bovine-derived collagen matrix product over the next two years.

E-Commerce and Account Management Platform

MiMedx launches its MiMedx Connect wound care management portal which provides access to online ordering and reimbursement tracking. Providers that use MiMedx product can place orders, verify insurance coverage, track orders and manage patient reimbursement. The system is also connected to distributors and has a direct link to partner FedEx for order tracking.

Details of the new platform were provided in a March 13th press release. The goal of the portal is to simplify the interactions customers have with MiMedx and to reduce administrative burden and provide a centralized hub for access to account information and resources. The platform also provides product information for each of MiMedx' products. At the time of the press release, over 300 customer locations were using the hub and feedback from customers has been positive.

New Directors

As of March 1st, 2024, MiMedx appointed two new independent directors to the MiMedx board of directors, increasing the size of the board to 11. The first of the new additions is Tiffany Olson, who has experience as CEO, President and other senior leadership roles at Cardinal Health, Roche and Eli Lilly. She is also a board member for two other public companies, Telix Pharmaceuticals and Castle Biosciences, and the private company Langham Logistics. The second new board member is Dorothy Puhy, who has held board positions at Abiomed, Azenta, Eaton Vance, Reebok and other private companies. Executive experience includes CFO and COO of Dana-Farber Cancer Institute and COR of New England Medical Center (Tufts Medical Center). The board of directors anticipates that these new additions to their ranks will contribute to the company's strategic vision and provide valuable insights.

Milestones

- Conversion of Series B Convertible Preferred Stock – December 2023
- Attendance at TD Cowen Health Care Conference – March 2024
- Axiofill Request for Designation FDA response – end of 1Q:24
- Launch of xenograft product – 3Q:24
- Evaluation of new products and relationships - 2024

Summary

MiMedx continues to drive better than expected revenues and gross margins posting yet another beat to our estimates. Cash flows for 2024 are set up for a substantial improvement over 2023 levels. Investors have been watching the movements of the FDA and the MACs on changes that impact MiMedx' products. The dispute over the treatment of Axiofill is going to court and should be tied up in litigation over the next year. In the meantime, sales of Axiofill will continue. The MACs have continued to revise their proposals for skin substitute reimbursement. The most recent of these cuts out most of the skin products from reimbursement leaving only those with supportive clinical evidence. This is good news for MiMedx as two of its products made the list. While there is a comment period and the decision is not yet final, this should shift the balance of providers towards MiMedx product.

In other news, the company has launched an online e-commerce platform to streamline sales and added new directors, expanding the size of the board. With the recent conversion of the Series B and growing free cash flow, MiMedx has become incrementally more attractive in recent months especially when taking into account the most recent revenue beat and positive momentum for the rest of the year. We update our valuation to reflect a greater base for future growth increasing our valuation to $13.00 per share.

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement[2]

MiMedx Group, Inc.	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$321,477**	**$84,709**	**$89,586**	**$92,335**	**$97,339**	**$363,968**	**$425,843**	**$521,231**
YOY Growth	20.0%	18%	10%	13%	12%	13%	17%	22%
Cost of Goods Sold	$54,634	$12,987	$14,334	$14,774	$15,574	$58,235	$68,135	$83,397
Product Gross Margin	83.0%	84.7%	84.0%	84.0%	84.0%	84.0%	84.0%	84.0%
Selling, general & administrative	$211,124	$55,129	$53,341	$53,491	$55,500	$217,461	$220,179	$222,932
Investigation, restatement etc.	$5,176	$311	$0	$0	$0	$311	$0	$0
Research & development	$12,665	$2,841	$3,725	$3,740	$3,800	$14,106	$10,000	$6,000
Amortization of intangible assets	$762	$189	$191	$191	$191	$762	$369	$214
Other	$3,464	$54	$0	$0	$0	$54	$0	$0
Income from operations	$33,652	$13,198	$17,995	$20,139	$22,273	$73,039	$127,160	$208,689
Operating Margin	10%	16%	20%	22%	23%	20%	30%	40%
Interest (expense) income, net	($6,457)	($1,690)	($450)	($450)	($450)	($3,040)	($2,000)	($2,000)
Other income, net	($26)	($99)	$0	$0	$0	($99)	$0	$0
Pre-Tax Income	$27,169	$11,409	$17,545	$19,689	$21,823	$69,900	$125,160	$206,689
Provision for Income Tax	$36,806	($2,348)	($4,035)	($4,528)	($5,019)	($16,077)	($28,787)	($47,538)
Tax Rate	135.5%	-20.6%	23.0%	23.0%	23.0%	23.0%	23.0%	23.0%
Net Income	**$63,975**	**$9,061**	**$13,510**	**$15,161**	**$16,804**	**$53,823**	**$96,373**	**$159,150**
Net Margin	20%	11%	15%	16%	17%	15%	23%	31%
Reported EPS	**$0.44**	**$0.06**	**$0.09**	**$0.10**	**$0.11**	**$0.36**	**$0.63**	**$1.04**
YOY Growth						-18%	77%	64%
Basic Shares Outstanding	116,496	146,405	147,000	147,200	147,350	146,989	149,200	149,950
Fully Diluted Shares	145,962	150,028	150,100	150,100	150,100	150,082	152,000	153,000

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

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

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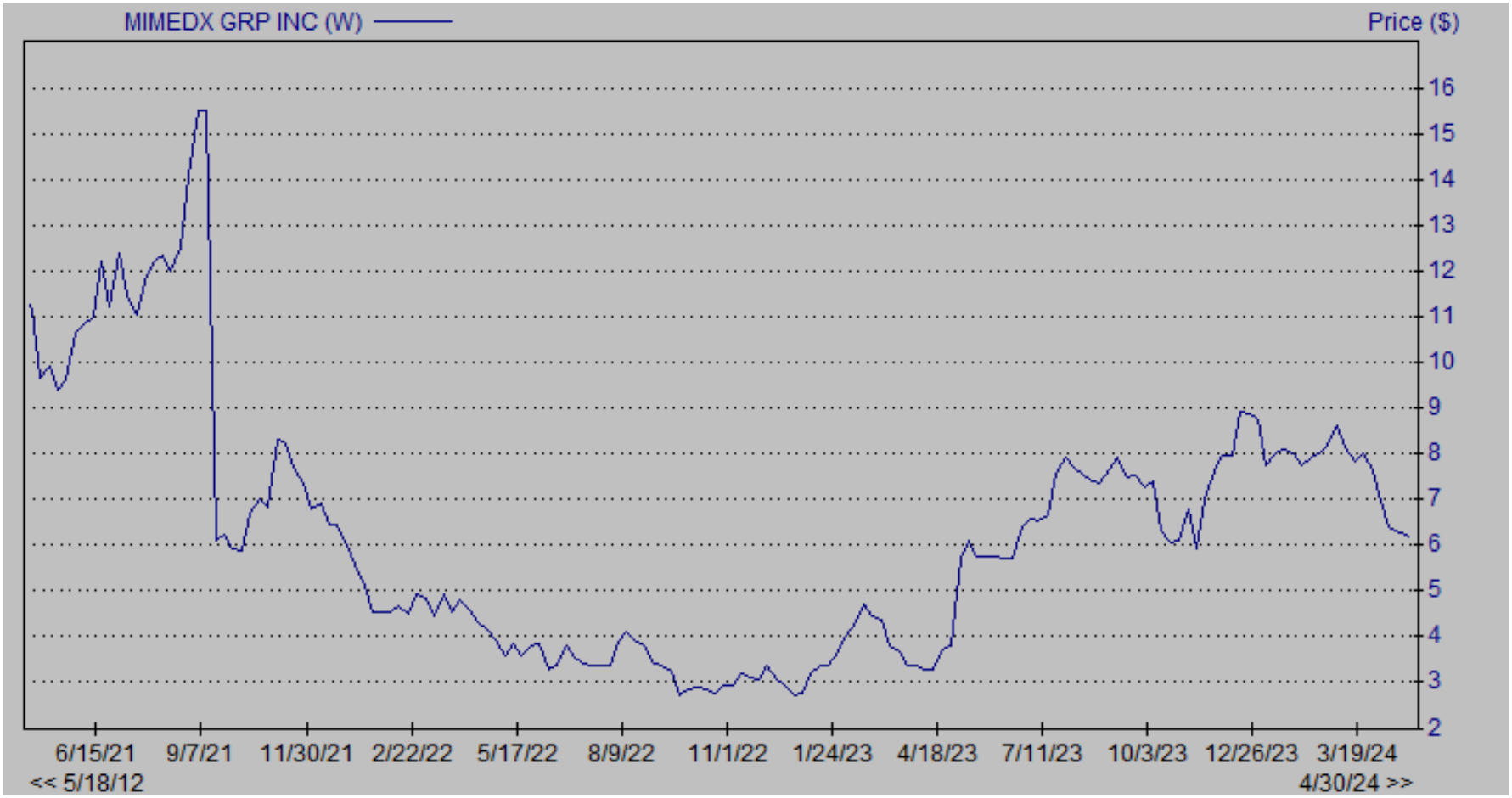
HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[3]



[3] Source: Zacks Research System

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