Zacks Small-Cap Research
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MiMedx Group, Inc. (MDXG: NASDAQ)

MDXG: Axiofill Update & Series B Conversion

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 (1/2/2024)	$7.87
Valuation	**$11.25**

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 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	**$2.90**
One-Year Return (%)	**165**
Beta	**1.7**
Average Daily Volume (sh)	**666,456**
Shares Outstanding (mil)	**149**
Market Capitalization ($mil)	**1,173**
Short Interest Ratio (days)	**5.8**
Institutional Ownership (%)	**56.1**
Insider Ownership (%)	**29.1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-2.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**57.5**
P/E using 2024 Estimate	**18.1**
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)
2022	$58.9 A	$66.9 A	$67.7 A	$74.4 A	$267.8 A
2023	$71.7 A	$81.3 A	$81.7 A	$85.2 E	$319.8 E
2024					$355.0 E
2025					$415.3 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.09 A	-$0.10 A	-$0.06 A	$0.00 A	-$0.21 A
2023	-$0.03 A	$0.01 A	$0.07 A	$0.08 E	$0.11 E
2024					$0.34 E
2025					$0.61 E

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

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WHAT'S NEW

Corporate Updates

MiMedx Group, Inc. (NASDAQ: MDXG) has updated investors on two important events over the last few weeks. Most recently, the company announced that the FDA issued a Warning Letter related to Axiofill's classification as a Section 361 product. Recall that Axiofill was launched in Fall of 2022 as an acellular human placental extracellular matrix (ECM) derived from the placental disc intended for use in surgical recovery procedures. The company has also announced that its Series B Convertible Preferred Stock has been converted to common stock, substantially simplifying its balance sheet. Since our third quarter update the company has also attended conferences and published data related to clinical outcomes and cost effectiveness in the treatment of venous leg ulcers.

Axiofill Letter

In a year end press release, MiMedx announced that the FDA had issued a warning letter related to the classification of Axiofill as a Section 361 product. The warning letter does not relate to any other MiMedx products and does not raise any concerns related to product safety or adverse events. Axiofill is expected to generate less than 5% of total net sales in 2023 and this event is not expected to have any impact on 2023 sales. 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. MiMedx is answering agency questions related to the RFD and will submit the compiled data when the questions are resolved. Following acceptance of the RFD, the FDA has 60 days to make a final determination. If the response is unfavorable, MiMedx may appeal. During this process Axiofill sales will continue. We anticipate only a minor impact to 2024 sales assuming the resolution is negative.

One of MiMedx' arguments for Section 361 classification relates to competing product Interfyl connective tissue matrix, which is a placental-derived, allogeneic, decellularized, dehydrated particulate similar in manufacture and use to Axiofill. MiMedx asserts that since Interfyl is a similar product and classified under Section 361 that Axiofill should be treated similarly.

- 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

Conversion of Series B Convertible Preferred Stock

In a December 28th press release, MiMedx announced that 95,000 shares of Series B Convertible Preferred Stock were converted into common equity shares of the company. The convertibles were issued in July 2020 to an affiliate of EW Healthcare Partners and certain funds managed by Hayfin Capital Management. Terms of the security allowed it to be converted by the holder at any price above $3.85. Conversion is required after July 2, 2023 if MiMedx shares trade above $7.70 for 20 out of 30 trading days. By late December, the forced conversion requirement was reached and approximately 30 million shares have been added to equity shares outstanding. In addition to simplifying the balance sheet, this transaction allows MiMedx to avoid the payment of the stock dividend that has accrued over the last three years.

Valuation

We update our valuation to reflect a potential change in Axiofill sales and the updated share balance from the Series B conversion. We reduce our 2024 revenue estimates by 100 basis points or $3.2 million. If Axiofill is not ultimately classified as Section 361 product, the impact will likely be felt only in the second half. Substitute products may make up some of the difference and we are optimistic that acquisitions remain on the horizon, which can leverage the company's in-place sales force. We modestly reduce shares outstanding to reflect the updated share balance and halt to the share dividend owed the Series B holders. The net result of our change does not affect our valuation and our target remains at $11.25.

Conferences and Presentations

MiMedx attended the Symposium on Advanced Wound Care (SAWC) Fall meeting November 2-5 in Las Vegas, Nevada. The company also hosted a booth as an exhibition for attendees. In a presentation session, faculty presenters Drs. Nicholas Mouawad, William Tettelbach and Naz Wahab reviewed recent data examining the clinical and economic impacts of using skin substitutes in the treatment of Venous Leg Ulcers as well as published data evaluating the impact of adequate debridement in the treatment algorithm of chronic wounds and how it translates to clinical outcomes. The title of the presentation was *Bringing the Data into Focus: Optimizing Clinical Outcomes and Cost-Effectiveness in the Treatment of Venous Leg Ulcers*. MiMedx presented nine other posters at the event which reviewed the use of dehydrated human amnion chorion membrane (DHACM) in a variety of settings among other topics.

MiMedx also participated in several investor conferences in the last quarter of 2023. This included the Craig-Hallum Capital Group Annual Alpha Select Conference on November 16th, the Mizuho Medical Device and Healthcare Services Summit on December 6th and the Stifel MedTech Annual West Coast Bus Tour on December 14th.

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement[1]

MiMedx Group, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$267,841**	**$71,676**	**$81,257**	**$81,712**	**$85,159**	**$319,804**	**$354,983**	**$415,330**
YOY Growth	4%	22%	21%	21%	15%	19%	11%	17%
Cost of Goods Sold	$48,316	$12,419	$13,583	$14,790	$13,626	$54,418	$56,797	$66,453
Product Gross Margin	82.0%	82.7%	83.3%	81.9%	84.0%	84.0%	84.0%	84.0%
Selling, general & administrative	$208,789	$52,279	$51,925	$52,571	$56,957	$213,732	$216,404	$219,109
Investigation, restatement etc.	$12,177	$3,673	$1,017	($38)	$0	$4,652	$0	$0
Research & development	$22,829	$6,496	$8,497	$3,175	$1,500	$19,668	$6,000	$6,000
Amortization of intangible assets	$701	$190	$191	$190	$172	$743	$688	$600
Other	$0	$0	$3,256	$208	$0	$3,464	$3,603	$0
Income from operations	($24,971)	($3,381)	$2,788	$10,816	$12,905	$23,128	$71,491	$123,768
Operating Margin	-9%	-5%	3%	13%	15%	7%	20%	30%
Interest income, net	($5,016)	($1,553)	($1,630)	($1,680)	($1,651)	($6,514)	($5,000)	($3,500)
Other income, net	($4)	$2	($32)	($11)	($2)	($43)	$0	$0
Pre-Tax Income	($29,991)	($4,932)	$1,126	$9,125	$11,251	$16,570	$66,491	$120,268
Provision for Income Tax	($206)	($51)	$74	($591)	$0	($568)	($15,293)	($27,662)
Tax Rate	0.7%	0.0%	0.0%	0.0%	0.0%	-3.4%	23.0%	23.0%
Net Income	**($30,197)**	**($4,983)**	**$1,200**	**$8,534**	**$11,251**	**$16,002**	**$51,198**	**$92,607**
Net Margin	-11%	-7%	1%	10%	13%	5%	14%	22%
Reported EPS	**($0.21)**	**($0.03)**	**$0.01**	**$0.07**	**$0.08**	**$0.11**	**$0.34**	**$0.61**
YOY Growth	127%						195%	79%
Basic Shares Outstanding	112,909	114,399	115,866	116,298	148,000	123,641	151,000	152,500
Fully Diluted Shares	142,469	143,959	145,864	119,328	148,000	139,288	151,000	152,500

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

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

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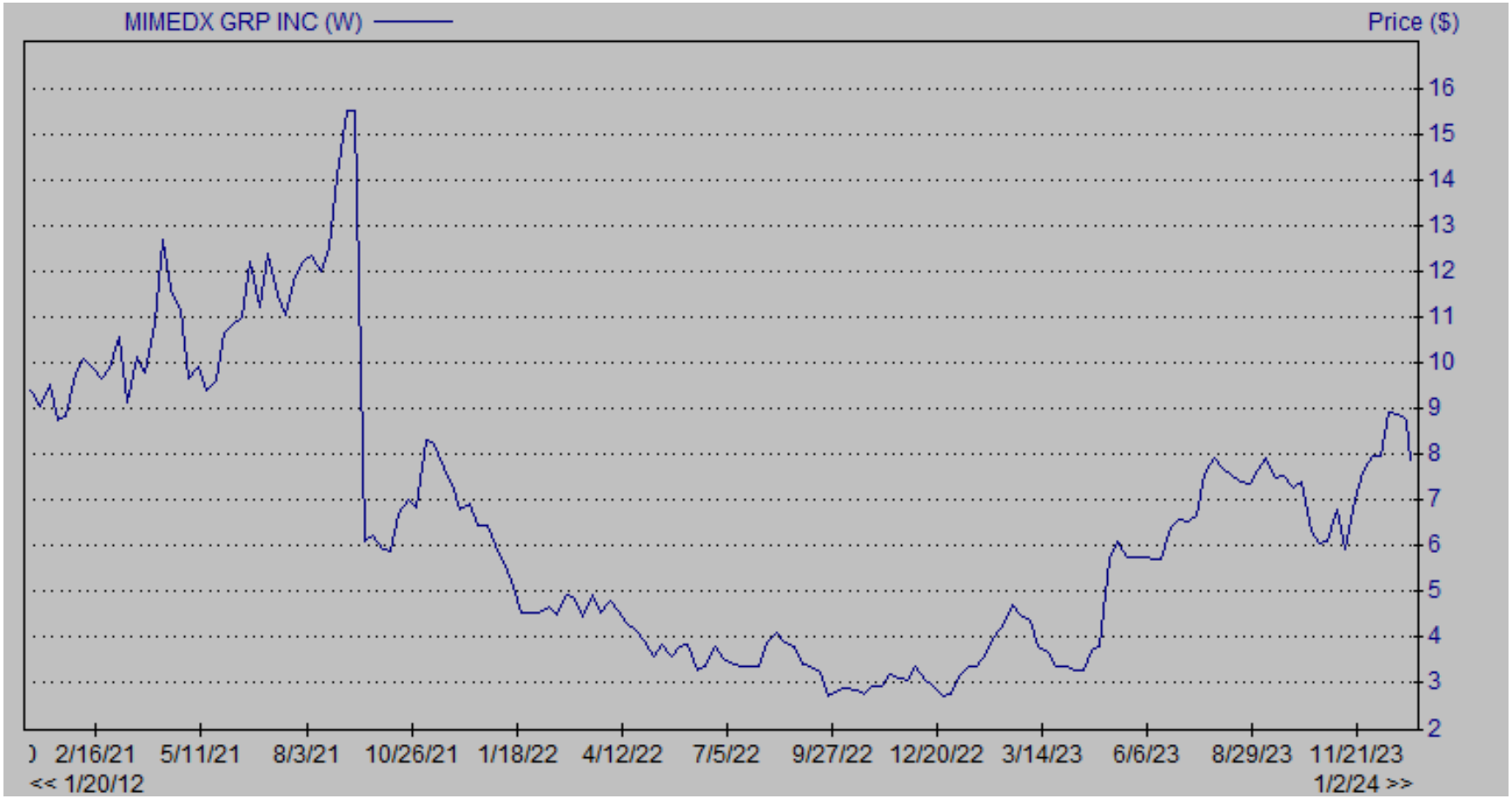
HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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