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November 3, 2022
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MiMedx Group, Inc. (MDXG: NASDAQ)

KOA Trial Launch Around the Corner

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 (11/2/2022)	$2.76
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. Phase III clinical trials are anticipated in late 2022/early 2023 for 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	**$8.70**
52-Week Low	**$2.59**
One-Year Return (%)	**-60.7**
Beta	**1.78**
Average Daily Volume (sh)	**530,360**
Shares Outstanding (mil)	**142**
Market Capitalization ($mil)	**392**
Short Interest Ratio (days)	**6.5**
Institutional Ownership (%)	**62.5**
Insider Ownership (%)	**4.2**
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	**14.9**
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	$74.2 E	$267.6 E
2023					$315.8 E
2024					$366.3 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 E	-$0.20 E
2023					$0.18 E
2024					$0.33 E

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

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WHAT'S NEW

3Q:22 Financial and Operational Results

After market close on November 2, 2022, MiMedx Group, Inc. (NASDAQ: MDXG) filed its Form 10-Q with the SEC and issued a press release summarizing its financial and operational results for the quarter ended September 30, 2022. A conference call and webcast were held following the release to communicate additional detail to analysts and investors.

3Q:22 is the first quarter for MiMedx that does not require prior year adjustment to account for Section 351 product which was not sold domestically after May 31, 2022. The company continued to show topline growth in its core business and produced 7.3% increase overall driven by sales in the surgical recovery market and contributions from Amnioeffect™ and Axiofill™. Highlights since the beginning of the third quarter and to date include multiple new leadership additions including a new Chief Executive Officer, a new Chief Human Resources Officer, a new Head of Investor relations and the formation of a Regenerative Medicine Scientific Advisory Board. Other accomplishments include reimbursement approval in Japan and the launch of new products Axiofill and Amnioeffect. The key upcoming item expected around year-end is the start of the knee osteoarthritis (KOA) trial.

Revenues and net loss for the third quarter were $67.7 million and ($8.4) million with net loss available to common stockholders was ($10.1) million with the difference attributable to the dividend on the Series B convertible stock. Net loss per share was ($0.06) and for common stockholders ($0.09). These results compare to net loss of ($0.04) generated in 3Q:21.[1]

For the quarter ending September 30, 2022, compared to the one ending September 30, 2021:

- Reported revenues were $67.7 million, up 7.3% from $63.1 million. Revenue increased on expanding sales from the surgical recovery segment and contributions from Amnioeffect and Axiofill;
- Gross margin declined by approximately 200 basis points to 82.0% from 83.9% on lower production levels;
- SG&A was $53.5 million, up 15.5% from $46.3 million reflecting higher commissions and increased levels of travel compared to 3Q:21. Additionally, the third quarter of 2022 included higher personnel costs associated with severance expense related to the former CEO, and consulting expenses related to various market assessments conducted as part of the company's strategic planning process;
- Investigation, restatement and related expenses were $3.0 million, down from $3.2 million;
- R&D expenses were $6.0 million, increasing 36% from $4.4 million, related to higher costs associated with the KOA clinical program as well as higher development and testing costs incurred in anticipation and support of the Amnioeffect and Axiofill new product launches.;
- Operating loss was ($7.1) million vs ($1.1) million;
- Interest expense was ($1.3) million versus ($1.0) million;
- Net loss was ($8.4) million versus ($2.3) million, or ($0.06) per share versus ($0.02) per share;
- Net loss available to common stockholders was ($10.1) million vs ($3.9) million or ($0.09) and ($0.04).

As of September 30, 2022, cash stood at $73.2 million, a slight increase from 2Q:22 levels resulting from positive free cash flow. Debt was carried on the balance sheet at $48.5 million. Free cash flow for the quarter was $585,000 compared to a contribution of $5.7 million in the prior year period. 2021 cash flows were boosted by a tax refund of $9.2 million while 2022 flows were reduced by a $2 million milestone payment to Nordic Bioscience Clinical Development. Adjusted EBITDA, as calculated by the company which adds back costs incurred related to the investigation and restatement and share based compensation, was ($724,000) which compares to prior year contribution of $7.0 million. Third quarter EBITDA calculated by the company and Zacks was ($6.1) million and $41,000 for the 2022 and 2021 periods respectively.

New Products Adding to Revenues

In late September, MiMedx announced the launch of two new products and the receipt of reimbursement approval in Japan. On September 20, Axiofill, an extracellular matrix (ECM) particulate product derived from human placen-

[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.

tal tissue was launched. The day prior, Amnioeffect was fully launched, following limited distribution a few months earlier. Epifix was granted reimbursement approval in Japan as shared in a September 12th release. Full product launch is expected in 4Q:22.

Each of the products was released later than expected due to low staffing levels at hospitals related to post-COVID recuperation and vacation related absences. Regulatory delays in Japan contributed to the later than expected reimbursement approval. Distributors in Japan will not enter into agreements for products until the reimbursement details are clear. Training must also take place before sales, another factor that has delayed the recognition of revenues for Epifix in Japan until 4Q:22. The net result of these delays is that minimal new product sales contributed to 3Q:22 revenues and year over year growth was predominantly organic in the third quarter.

Axiofill is an acellular human placental extracellular matrix (ECM) derived from the placental disc intended for use in surgical recovery procedures. It preserves several ECM components and other matrix-bound proteins and can be used in replacement or supplementation of damaged or inadequate integumental tissue. The product's features include versatility in application, support from clinical trials and the ability for use in negative pressure wound therapy (NPWT) and hyperbaric oxygen therapy (HBOT). MiMedx estimates market size for xenograft products at $230 million. The product is distinguished from other solutions in that it is able to address an uneven surface defect or a deep, tunneling wound.

Exhibit I – Use and Formulation of Axiofill[2]



Amnioeffect is a thick human amnion, intermediate layer and chorion allograft. It provides a semi-permeable protective barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue. The product protects the wound bed to aid in the development of granulation tissue by creating a semi-permeable protective barrier. Amnioeffect is biocompatible and contains over 300 regulatory proteins. It is in sheet form and is suitable for a number of clinical uses from amputations to minimally invasive surgery.

Exhibit II – Use and Form of Amnioeffect[3]



[2] Source: MiMedx company website accessed September 2022.
[3] Source: MiMedx company website accessed September 2022.

Epifix has been sold in the United States for some time and is now available in Japan following the reimbursement approval in that territory. This provides MiMedx access to an estimated $500 million and 400,000 patient hard to heal wound market for the treatment of refractory diabetic and venous ulcers. It 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.

K. Todd Newton Appointed as Interim CEO

On September 6, 2022, MiMedx Group, Inc. (NASDAQ: MDXG) announced that Timothy R. Wright had departed the lead management role and would be replaced by board of director member K. Todd Newton. Mr. Newton has served on the MiMedx board since 2019 holding the roles of Chair of the Audit Committee and as member of the Ethics and Compliance Committee. He has previous executive experience as CEO of Apollo Endosurgery (NASDAQ: APEN) where he led the device company for seven years. Previously he was CFO and COO at Arthro-Care Corporation. He has also held roles at Syneco Energy and Deloitte & Touche.

The board highlighted Mr. Newton's near 20 years of public company senior leadership experience and his guidance of the MiMedx management team on financial reporting and performance issues. Looking ahead, he will assist the board with its ongoing strategic review and continue to lead the company in its growth trajectory. A search committee has been formed to identify a permanent CEO comprised of board members M. Kathleen Behrens, James L. Bierman and William A. Hawkins III. An as yet unidentified search firm will assist in the process.

Dr. Laurencin Award

In late August, MiMedx board member, Dr. Cato T Laurencin, was recognized by the Regenerative Engineering Society with an award for his leadership and contributions to the field of regenerative engineering. The award is called The Cato T. Laurencin Regenerative Engineering Founders' Award. It was established by the American Institute of Chemical Engineers (AIChE) Foundation and the AIChE Regenerative Engineering Society to recognize accomplishments in the science and practice of convergence research as applied to regenerative engineering.

CMS Proposal for Skin Substitutes

30% 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. 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 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 will hold a meeting in early 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 HCPCS code C1849 to fall into the high-cost skin substitute group. For skin substitutes, CMS announced that it is not finalizing its proposal to change the terminology of skin substitutes and desires additional interaction with stakeholders prior to finalizing new terminology. The proposal is considering the elimination of Healthcare Common Procedure Coding System (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. Further updates from CMS and MiMedx are expected next year.

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
- Phase III KOA trials launch – late 2022/early 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 its third quarter results showing solid growth in its core wound care business that accelerated as the quarter progressed. Revenues for the reporting period rose 7.3% to $67.7 million which was sufficient to generate positive free cash flow. Fourth quarter is expected to produce revenues of $73 to $76 million and sufficient free cash flow to be neutral on the latter metric for the year. New products, new geographies and expansion of sales in surgical recovery are expected to drive the continued sales expansion. The company is in conversations with the FDA finalizing the protocol for the KOA trial and we expect to see the start of the trial around year end with the first patient enrolled in 1Q:23. 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[4]

MiMedx Group, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US '000)	**$258,615**	**$58,894**	**$66,883**	**$67,689**	**$74,150**	**$267,616**	**$315,787**	**$366,313**
YOY Growth	4%	-2%	-2%	7%	10%	3%	18%	16%
Cost of Goods Sold	$43,283	$9,936	$11,823	$12,188	$14,259	$48,206	$50,526	$58,610
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	$51,500	$210,338	$212,441	$215,097
Investigation, restatement etc.	$3,791	$2,552	$3,218	$3,001	$0	$8,771	$0	$0
Research & development	$17,345	$5,964	$5,512	$5,953	$6,150	$23,579	$20,000	$22,000
Amortization of intangible assets	$820	$172	$173	$175	$172	$692	$688	$688
Impairment of intangible assets	$53	$0	$0	$0	$55	$55	$0	$0
Income from operations	($5,037)	($9,300)	($9,636)	($7,103)	$2,014	($24,025)	$32,132	$69,918
Operating Margin	-2%	-16%	-14%	-10%	3%	-9%	10%	19%
Interest income, net	($4,980)	($1,126)	($1,170)	($1,270)	($1,500)	($5,066)	($5,000)	($5,000)
Other income, net	($23)	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($10,040)	($10,426)	($10,806)	($8,373)	$514	($29,091)	$27,132	$64,918
Provision for Income Tax	($246)	$63	($62)	($53)	$0	($52)	$0	($14,931)
Tax Rate	2.5%	0.0%	0.0%	0.0%	0.0%	0.2%	0.0%	23.0%
Net Income	**($10,286)**	**($10,489)**	**($10,868)**	**($8,426)**	**$514**	**($29,143)**	**$27,132**	**$49,987**
Net Margin	-4%	-18%	-16%	-12%	1%	-11%	9%	14%
Reported EPS	**($0.09)**	**($0.09)**	**($0.10)**	**($0.06)**	**$0.00**	**($0.20)**	**$0.18**	**$0.33**
YOY Growth	-80%	22.7%	496.9%	178.8%	-81.7%	119%	-190%	79%
Basic Shares Outstanding	110,353	111,616	112,868	113,448	114,500	113,108	132,563	152,000
Fully Diluted Shares	140,334	141,076	142,490	143,048	143,960	142,643	147,363	152,000

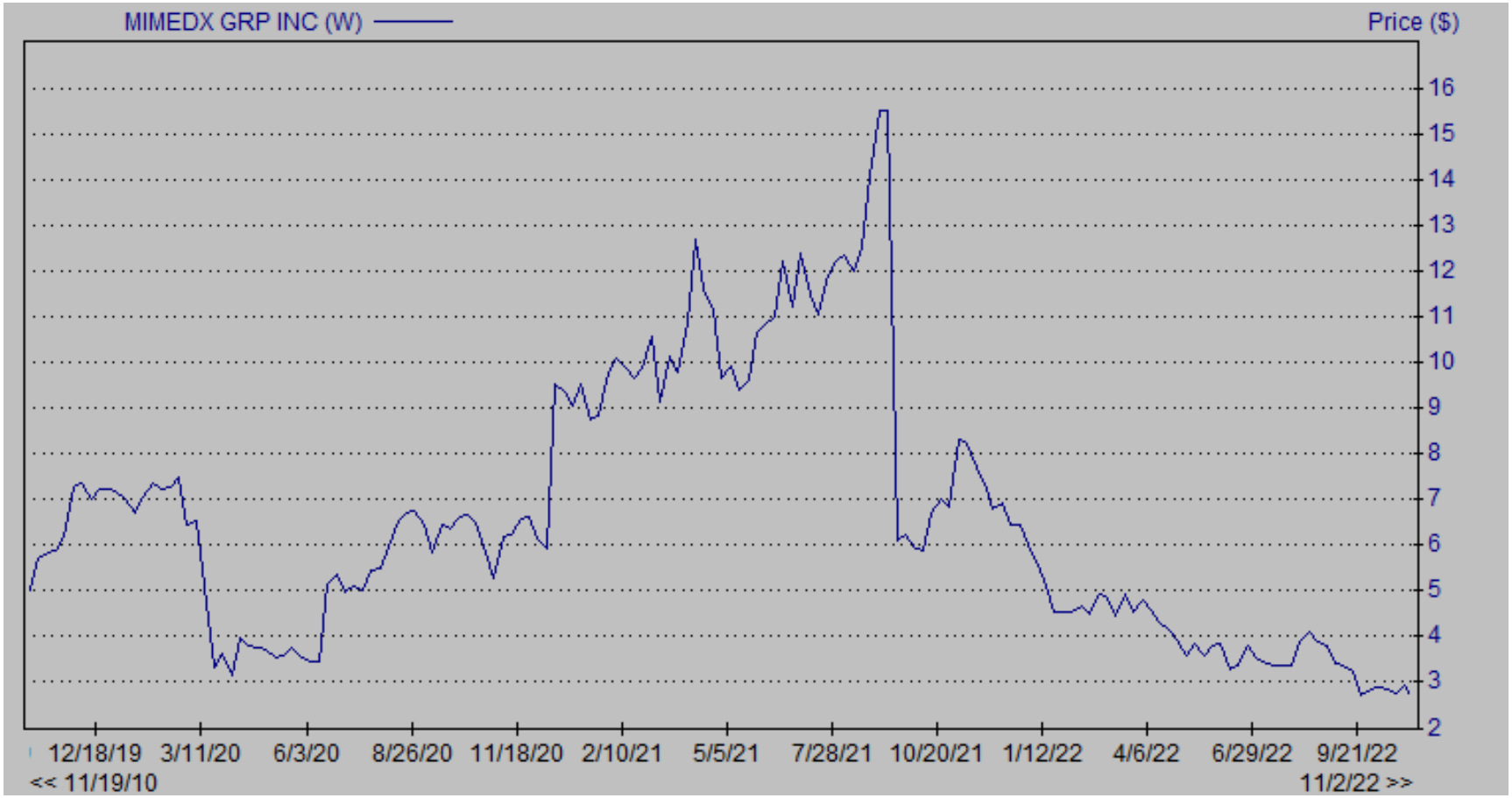
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[5]



[5] Source: Zacks Research System

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