

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): November 18, 2024

MIMEDX GROUP, INC.

(Exact name of registrant as specified in charter)

Florida
(State or other jurisdiction
of incorporation)

001-35887
(Commission
File Number)

26-2792552
(IRS Employer
Identification No.)

1775 West Oak Commons Ct., NE, Marietta GA 30062
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (770) 651-9100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	MDXG	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Important Cautionary Statement

This report includes forward-looking statements. Statements regarding: (i) future sales or sales growth; (ii) our 2024 and longer term financial goals and expectations for future financial results, including levels of net sales, Adjusted EBITDA, Adjusted EBITDA margin, corporate expenses and cash; (iii) our expectations regarding the placental tissue market; (iv) our expectations regarding Medicare spending and (v) continued growth in different care settings are forward-looking statements. Additional forward-looking statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “goal,” “outlook,” “potential,” “will,” “preliminary,” and similar expressions, and are based on management’s current beliefs and expectations.

Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Factors that could cause actual results to differ from expectations include: (i) future sales are uncertain and are affected by competition, access to customers, patient access to healthcare providers, the reimbursement environment and many other factors; (ii) the Company may change its plans due to unforeseen circumstances; (iii) the results of scientific research are uncertain and may have little or no value; (iv) our ability to sell our products in other countries depends on a number of factors including adequate levels of reimbursement, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (v) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (vi) we may alter the timing and amount of planned expenditures for research and development based on the results of clinical trials and other regulatory developments. The Company describes additional risks and uncertainties in the Risk Factors section of its most recent annual report and quarterly reports filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this report and the Company assumes no obligation to update any forward-looking statement.

Item 7.01 Regulation FD

Senior management of MiMedx Group, Inc. (the “Company”) is expected to participate in the Stifel 2024 Healthcare Conference on November 18, 2024 and the Craig-Hallum Capital Group 15th Annual Alpha Select Conference on November 19, 2024. A copy of the presentation materials to be made available by the Company in connection with the conferences is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this “**Current Report**”) and is incorporated herein by reference.

The information in this Current Report, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Slide Presentation dated November 2024
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MIMEDX GROUP, INC.

November 18, 2024

By: /s/ Doug Rice
Doug Rice
Chief Financial Officer



MIMEDX

Investor Presentation

November 2024

helping humans heal.

> Disclaimer & Cautionary Statements

This presentation includes forward-looking statements. Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Such forward-looking statements include statements regarding:

- Future sales, sales growth, profitability and Adjusted EBITDA margins;
- Estimates of potential market size and demand for the Company's current and future products;
- Plans for expansion outside of the U.S.;
- The effectiveness of amniotic tissue as a therapy for any particular indication or condition;
- Expected spending on research and development, including to innovate and diversify our product portfolio;
- Investments in data;
- Expectations regarding the reimbursement environment for the Company's products, including Medicare Spending;
- Manner of LCD implementation;
- Expectations regarding plans to reduce customer churn and enhancing customer relationships;
- Expectations that HELIOGEN will be a meaningful contributor to our financial performance in 2025;
- The stage of development of the placental-derived products market;
- The Company's long-term strategy and goals for value creation, the status of its pipeline products, expectations for future products, and expectations for future growth and profitability

➤ Disclaimer & Cautionary Statements

Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will," "preliminary," and similar expressions, and are based on management's current beliefs and expectations. Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Factors that could cause actual results to differ from expectations include:

- Future sales are uncertain and are affected by competition, access to customers, patient access to hospitals and healthcare providers, the reimbursement environment and many other factors;
- The future market for the Company's products can depend on regulatory approval of such products, which might not occur at all or when expected, and is based in part on assumptions regarding the number of patients who elect less acute and more acute treatment than the Company's products, market acceptance of the Company's products, and adequate reimbursement for such therapies;
- The process of obtaining regulatory clearances or approvals to market a biological product or medical device from the FDA or similar regulatory authorities outside of the U.S. is costly and time consuming, and such clearances or approvals may not be granted on a timely basis, or at all, and the ability to obtain the rights to market additional, suitable products depends on negotiations with third parties which may not be forthcoming; and
- The Company describes additional risks and uncertainties in the Risk Factors section of its most recent annual report and quarterly reports filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this presentation and the Company assumes no obligation to update any forward-looking statement.

> A Pioneer and Leader in Healing Solutions for Wound & Surgical

Our Why



Helping Humans Heal

Our Vision



To be the leading global provider of healing solutions through relentless innovation to restore quality of life.



placenta
donation
PROGRAM



The most studied portfolio of placental-based products with **50+** clinical & scientific publications and over **300 million** payer covered lives.

Large, national placental donation network and **proprietary tissue processing**.

New product innovations leading to untapped opportunities for growth, including an **increasing footprint in the Surgical market**.

A key partner to healthcare professionals with industry leading support services and **customer-focused approach**.

> The Unmet Need for Wound Healing Solutions Is Large and Growing



>10

million people suffer from chronic, non-healing wounds in the U.S.¹

Favorable Demographic Trends



- Aging population
- Obesity
- Smoking history
- Heart & vascular disease
- Diabetes

Chronic Wounds Burden Medicare Beneficiaries



~16% of the Medicare beneficiary population is impacted by chronic wounds—and this proportion is increasing.¹

Ineffective Wound Management Leads to Poor Outcomes



It is estimated that up to **85% of amputations are avoidable** with a holistic multispecialty team approach that incorporates **innovative treatments** and adherence to treatment parameters.²

Advances Driving Improved Outcomes for Patients



When applied following parameters for use, patients treated with **EPIFIX®** experienced reductions in **major amputations** and **hospital utilization**.²

5 1) Sen CK. Human Wound and Its Burden; Updated 2022 Compendium of Estimates. Adv Wound Care (New Rochelle). 2023;12(12):657-670.

2) Tettelbach WH, et al. Cost-effectiveness of dehydrated human amnion/chorion membrane allografts in lower extremity diabetic ulcer treatment. J Wound Care. 2022 Feb 1;31(Sup2):S10-S31.

Increasing Awareness of Massive Potential for Placental Tissue

The New York Times

Her Face Was Unrecognizable After an Explosion. A Placenta Restored It.

“Research has found placenta-derived grafts can reduce pain and inflammation, heal burns, prevent the formation of scar tissue and adhesions around surgical sites and even restore vision. They’re also gaining popularity as a treatment for the widespread issue of chronic wounds.”



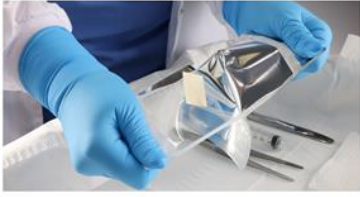
“...Tending to such wounds can be a matter of life and death for the millions of people with them, including 10.5 million Medicare beneficiaries as of 2022...”

“...The five-year mortality rate for people with one type, a diabetic foot ulcer, is close to 30 percent. That rate rises above 50 percent for those who require amputation.”



> The Patient Journey in Wound Care

MIMEDX products are available in all settings where patients receive care...



Private Office

Home Health

Mobile Health

Nursing Facility

Assisted Living Facility

Wound Care Clinic

Hospital Outpatient

Hospital Inpatient

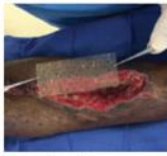
...and other care settings

...and are used on a range of chronic and other hard-to-heal wounds.

Acute Wounds



Mohs surgery



Burn/Trauma

Chronic Wounds



Diabetic Foot Ulcer



Venous Leg Ulcer

Complex/Dehisced Wounds



Limb Salvage



Dehiscence

Building Library of Evidence for Surgical Applications

Recent Publications Showcase Breadth of Potential Use Cases for MIMEDX Products in Surgery

Cranioplasty Procedures with AMNIOFIX®

Clinical Outcomes with Conventional Methods¹

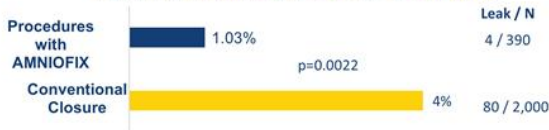


Clinical Outcomes with AMNIOFIX²



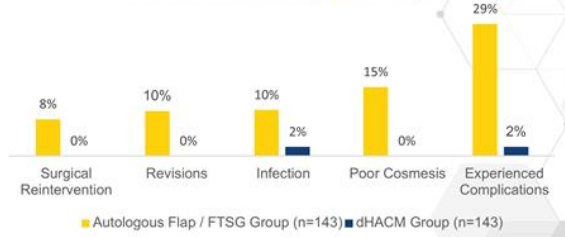
Colorectal Anastomoses Procedures with AMNIOFIX

Anastomotic Leak Rate with & without AMNIOFIX³



EPIFIX® in Mohs Procedures

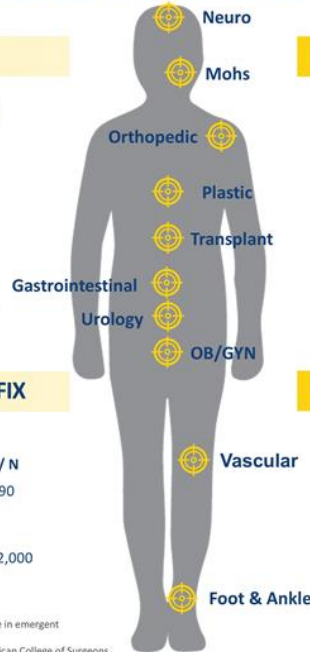
Peer-reviewed Retrospective Study⁴



AMNIOEFFECT® in Bunion Correction Surgery

Case Study⁵ – SAWC Fall 2023

The use of LHACM as a barrier membrane during Laplasty 3D Bunion Correction surgery is an effective strategy to improve surgical outcomes.



1) Lee B. MIMEDX interview with Bryan Lee, MD. October 4, 2023.
 2) Endicott L, Ehresman J, Tettelbach W, Forsyth A, Lee B. Dehydrated human amnion/chorion membrane (dHACM) use in emergent craniectomies shows minimal dural adhesions. *J Wound Care*. 2023;32(10):634-640.
 3) F. Raymond Ortega, MD, FACS; Dennis Choat, MD, FACS, FASCRS; Emery Minnard, MD; Jeffrey Cohen, MD. The American College of Surgeons Clinical Congress, Oct 22-26, 2017, San Diego, CA.
 4) Toman J. *Facial Plast Surg Aesthet Med*. 2022;24(1):48-53.
 5) Franklin Polun, DPM, DABFAS, FAFAS FAFAS; Jake Michaelson. Symposium on Advanced Wound Care Fall, Nov 2-5, 2023, Las Vegas, NV.

Additional Surgical Studies in Process Focused on Significant Clinical Opportunities



EPIFIX Mohs HECON

Accepted for Publication

EPIFIX used in Mohs procedures associated with **avoidance of postoperative complications and ancillary procedures**, compared to patients treated with standard of care



AMNIOFIX in GI Anastomosis

Manuscript Pending

Seeking to demonstrate **reduction in the rate of leaks** when using placental allografts



AMNIOFIX in Liver Transplant

RCT Enrollment Underway

Evaluating utility of placental allografts to **help reduce biliary complications, improve healing and reduce fibrosis**



AMNIOFIX in Breast Reduction

RCT Enrollment Underway

Wound breakdown rates are a common complication of large volume breast reductions and could benefit from utilizing placental tissue

> Our Strategic Priorities

> Innovate & Diversify Product Portfolio to Maximize Growth

- Continue momentum with new organic products in Wound & Surgical
- Consider additional inorganic additions to our product offering
- Drive further uptake of EPIFIX® in Japan

> Develop & Deploy Programs to Expand Footprint in Surgical

- Increase our presence in targeted surgical settings with our portfolio
- Invest in clinical data, partnering with KOLs

> Enhance Customer Intimacy

- Execute on initiatives to increase customer “stickiness” and reduce churn



helping humans heal.

Expanding Breadth of Skin Substitutes

Leading Human-Derived Portfolio



Best-in-Class Wound Product Portfolio



Innovative Offering for Surgical Market

Emerging Xenograft Platform



Recently announced exclusive manufacturing and supply agreement with Regenity Biosciences.

HELIOGEN builds on our goal to augment our growth through strategic portfolio expansion.

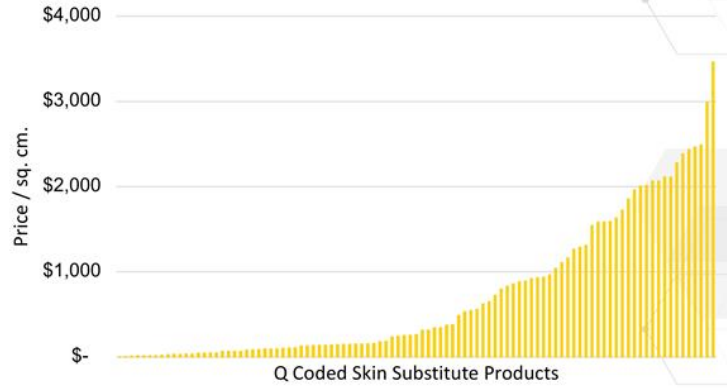
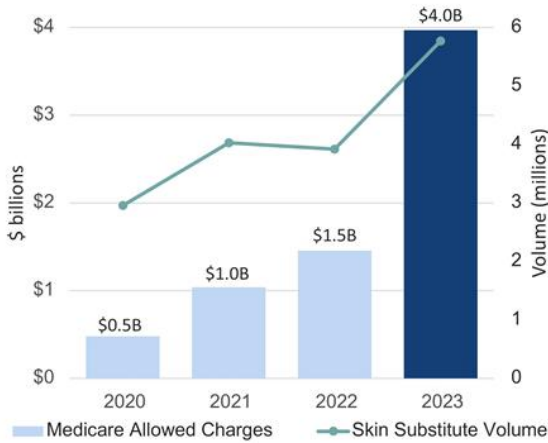
Provides MIMEDX with a bovine-derived collagen matrix particulate product that is 510(k)-cleared and indicated for the management of exuding wounds and to control minor bleeding.

Worsening Medicare Spending Crisis Underscores Need for Overhaul

Medicare Allowed Charges¹ for skin substitutes have **exploded** since 2020...

...as have the number of skin substitutes on the Medicare ASP List², with a **significant number of products priced >\$1,000/sq.cm...**

...resulting in run rate spend of **over \$1 billion of spend PER MONTH** on products in the category



LCDs Represent Needed First Step to Curb Abuses in Private Office & Associated Care Settings

1) The Moran Company, (2024). Volume and Total Payment by Skin Substitute Product, CY 2019-2023.
 2) ASP List refers to the Medicare Part B ASP Drug Pricing Files and CMS refers to the Centers for Medicare and Medicaid Services, Data Source: ASP Pricing Files. Centers for Medicare & Medicaid Services. Accessed March 18, 2024.
<https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>
 3) LCDs refer to "Local Coverage Determination"

> LCDs Represent Critical First Step for Medicare Payment Overhaul

Recently Updated LCDs Require Robust Clinical Data for Medicare Coverage

Initially proposed in April 2024, **extensive comment period** enabled industry stakeholders to participate in rulemaking

MIMEDX's **engaged in advocacy with CMS, MACs & Congress to urge action** to rein in runaway Medicare spend on skin substitutes

LCDs intended to encourage use of products with **data and proven efficacy**

Provides Medicare Trust Fund with short-term solution to **curb runaway spending on skin substitutes**

Key Revisions from Proposed LCD Include:

Applications

4 → 8

Products Eligible for Reimbursement Include

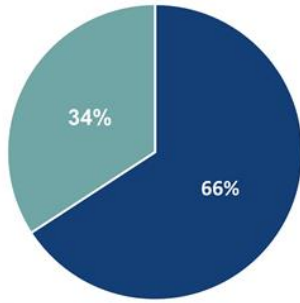
EPIFIX® & EPICORD®

Effective Date

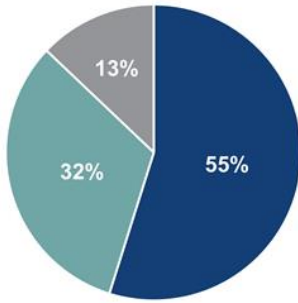
Feb. 12, 2025


Additional reform still needed from CMS through modifications to the physician fee schedule

> Diversified Business by Product & Across Multiple Sites of Service



Product Type	Segment Commentary
 Wound	Led by best-in-class placental allograft, EPIFIX and our newest product innovation, EPIEFFECT®
 Surgical	Continuing to see expanding use cases for allografts and xenografts in a large and growing number of surgical settings



Site of Service	Segment Commentary
 Hospital Setting (Inpatient & Outpatient) & Wound Care Clinics	Stable reimbursement settings and growing with expanded use of products in surgical applications
 Private Office	Medicare reimbursement evolving, resulting in opportunity for EPIFIX & EPICORD
 Other	Derived from other sites of service, including federal facilities and international

Commercial Organization with Scale, Leverage & Extensive Reach

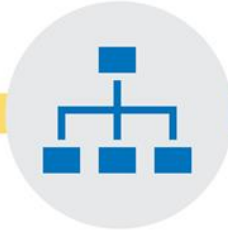
Over **200** direct sales professionals nationwide



Extensive corporate support network



Over **75** agencies with **200+** agents nationwide



Experience selling more than **3** million allografts



Over **300** million payer lives covered



Growing presence in **Japan**

Q3:24 Highlights

Net Sales
\$84MM
+3% year-over-year

Gross Margin
82%

GAAP Net Income
\$8MM

Adjusted EBITDA¹
\$18MM
22% of net sales

Cash Balance
\$89MM
+\$20MM vs. Q2:24

Continued Market Release of
HELIOGEN™

Lawmaker Engagement to Drive Reimbursement Reform

Patient Stories Recently Featured
The New York Times

Management Team with Track Record of Success in MedTech



Joe Capper
Chief Executive Officer



Doug Rice
Chief Financial Officer



Kim Moller
Chief Commercial Officer



John Harper, Ph.D.
Chief Scientific Officer & SVP, R&D



Ricci Whitlow
Chief Operating Officer



Butch Hulse
Chief Administrative Officer & General Counsel



Kate Surdez
Chief Human Resource Officer



Matt Notarianni
Head of IR

Prior Roles Include:



➤ Conclusion

**Large & expanding
addressable markets**

**Maturing
reimbursement &
regulatory landscape**

**Competitive advantage
with defensible IP and
proprietary technology**

**Strong & improving
financial profile &
balance sheet**

**Experienced & skillful
leadership team more
than capable of
executing strategy**

helping humans heal.

MIMEDX