

**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): June 30, 2022

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.

Item 7.01 Regulation FD

On June 30, 2022, MiMedx Group, Inc. (the “Company” or the “Registrant”) issued a Letter to Shareholders from its Chief Executive Officer, Timothy Wright, which 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 | Letter to Shareholders dated June 30, 2022. |
| 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.

Date: June 30, 2022

By: /s/ Peter M. Carlson
Peter M. Carlson,
Chief Financial Officer



June 30, 2022

Dear Shareholder,

On behalf of the Board of Directors, I thank you for your support at our recent 2022 Annual Meeting of Shareholders. We value regular, candid and open shareholder engagement, and appreciate the constructive feedback received during the last months. We remain committed to working in your best interests.

We have taken decisive action to successfully sustain, stabilize and grow MIMEDX, and execute our strategy for long-term shareholder value creation. Today, we are a stronger, more reputable Company with reliable and experienced leadership that is responsible for driving growth, execution, and performance:

1. Double-digit Growth and Market Expansion:

- We delivered our third consecutive quarter of double-digit growth in our Advanced Wound Care & Surgical Recovery portfolio — a testament to strong strategic execution and commitment to growth.
- We appointed a General Manager, Mr. Takanori Kuramoto, to lead our global market expansion efforts in Japan and other Asia Pacific markets. We are well-positioned to expand our global reach, operationalize the launch of EPIFIX® in Japan upon obtaining reimbursement approval, and address the needs of this substantial market.

2. Pipeline Execution: We are advancing two promising pipelines that leverage our placental tissue platform. Our Regenerative Medicine pipeline is focused on a potentially disruptive new therapeutic biologic for the treatment of Knee Osteoarthritis (KOA). Our Wound Care & Surgical Recovery pipeline is advancing innovation to meet worldwide unmet needs in chronic and acute wounds. Our recent progress is significant:

- We engaged Nordic Bioscience Clinical Development A/S (NBCD), a world-class contract research organization (CRO) specializing in Osteoarthritis clinical trials and Image Analysis Group, an expert imaging company, to propel registrational trials of our placental biologic injectable forward for KOA. We plan to use Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain and WOMAC Function as co-primary endpoints.
- We introduced AMNIOEFFECT™, with the first patient treated in a limited market release, as part of our 2022 objectives to improve the Company's Product Vitality Index. MIMEDX is committed to bringing innovative, organic products to market that address unmet and underserved medical needs, and with the introduction of AMNIOEFFECT, we are advancing this key component of our growth strategy. AMNIOEFFECT is the first of two new products we plan to bring to market in 2022 as we expand into the Surgical Recovery market and strengthen our portfolio of leading placental technologies.

3. Culture for Performance: Strong and ethical internal culture drives powerful performance in the market. Our realigned business structure provides a solid foundation to further expand, innovate, and drive sustained growth. MIMEDX is growing, creating value and poised for even greater success.

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There is more to do and we are committed to sustained progress. We are relentless in our efforts to demonstrate performance and meaningfully enhance shareholder value. We will continue to include shareholder input and constructive feedback in our strategic decision-making.

We also are committed to responsible business practices and the highest ethical standards, with integrity as a critical component of our core values. In the months leading up to this year's Annual Meeting, information from outside parties presented factually erroneous statements, misrepresented our progress, and distorted our future plans. We encourage you to review the information that MIMEDX directly reports. It is important to set the record straight that MIMEDX has **never** used expired products in our clinical trials. The Company has repeatedly acknowledged, based on a thorough root-cause analysis, the potency of the investigational product used in its Phase 2B Knee Osteoarthritis study faded as it aged. The Company is confident in its manufacturing processes and proprietary tissue engineering know-how and has a clear path forward. It is unfortunate this kind of information was distorted and disseminated. Knowingly using expired products in any clinical setting is something MIMEDX has never done and will never do.

Our forward momentum is future-focused. It has taken years of hard work to establish the Company's now solid foundation. As we reflect on our Company today, we are proud of the significant progress we have made and hold a clear strategic vision for our future with a restored Company reputation. We have the opportunity to reinvigorate our Product Vitality Index, optimize the value of our placental biologics pipeline asset, and expand our business in support of our mission to improve people's health and lives through innovation, as well as create significant value for all shareholders. Our Board and management team remain confident in the steps we are taking to enhance the value of MIMEDX. We are determined and forward-thinking, and invite you to share in our optimism about the next phase of growth.

Thank you for your support of MIMEDX and the trust you have placed in our team to protect and enhance your investment. We look forward to sharing our continued progress with you.

Sincerely,

Timothy R. Wright
MIMEDX Chief Executive Officer

Important Cautionary Statement

This letter includes forward-looking statements. Statements regarding: (i) our confidence in the steps we are taking to enhance the value of MIMEDX; (ii) our plans for product launches in 2022 and beyond; (iii) our belief that we are well positioned to operationalize our launch of EPIFIX upon obtaining reimbursement approval in Japan; (iv) our belief that our realigned business structure provides a solid foundation to further expand, innovate, and drive sustained growth, and that we are poised for greater success; and (v) our never knowingly using expired products in any clinical setting in the future. 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, and many other factors; (ii) the status, timing, results, and expected results of the Company's clinical trials, planned regulatory submissions and regulatory approvals, and our expectations regarding our ability to potentially accelerate the timing of any trial or regulatory submission, depend on a number of factors including favorable trial results, patient access, and our ability to manufacture in accordance with Current Good Manufacturing Practices (CGMP) and appropriate chemistry and manufacturing controls; (iii) the Company may change its plans due to unforeseen circumstances, or delays in analyzing and auditing results, and may delay or alter the timeline for future trials, analyses, or public announcements; (iv) our access to hospitals and health care provider facilities could be restricted as a result of the ongoing COVID-19 pandemic or other factors; (v) the results of scientific research are uncertain and may have little or no value; (vi) our ability to sell our products in other countries depends on a number of factors including adequate levels of reimbursement, regulatory approvals, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (vii) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (viii) 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 letter and the Company assumes no obligation to update any forward-looking statement.

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