UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

SCHEDULE 14A
(Rule 14a-101)

INFORMATION REQUIRED IN
PROXY STATEMENT

SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934

Filed by the registrant Filed by a party other than the registrant

Check the appropriate box:

		Preliminary Proxy Statement
		Confidential, for use of the Commission only (as permitted by Rule 14a-6(e)(2))
		Definitive Proxy Statement
		Definitive Additional Materials
☒		Soliciting Material Pursuant to §240.14a-12

MIMEDX GROUP, INC.

(Name of registrant as specified in its charter)

Payment of the filing fee (check the appropriate box):

☒		No fee required.		
		Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.		
		(1)		Title of each class of securities to which transaction applies:
		(2)		Aggregate number of securities to which transaction applies:
		(3)		Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
		(4)		Proposed maximum aggregate value of transaction:
		(5)		Total fee paid:
		Fee paid previously with preliminary materials.		
		Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.		
		(1)		Amount previously paid:
		(2)		Form, Schedule or Registration Statement No.:
		(3)		Filing party:
		(4)		Date filed:

On May 3, 2021, the Registrant published the following letter:

May 3, 2021

Dear Healthcare Professional,

MIMEDX is reaching out so that you are aware of an important U.S. Food and Drug Administration (FDA) category-wide announcement on the availability of certain regenerative medicine products, and their safe and effective use. We have been preparing for this development for some time and follow regulatory guidelines closely to best serve our customers. We are your partner in addressing patient needs and want you to know first-hand about these FDA policies and how MIMEDX is working to ensure continuity of care.

BACKGROUND INFORMATION:

In November 2017, the FDA outlined a regenerative medicine policy to set out the regulatory approval pathways for certain human cells, tissues, and cellular and tissue-based products (HCT/Ps), and future approval requirements to market these products for specific uses or indications. This FDA policy covered products that do not meet the Section 361 HCT/Ps definition for “minimal manipulation” and “homologous use.” After May 31, 2021, FDA will no longer exercise enforcement discretion and will regulate these products under the applicable classification of drugs, devices and/or biological products subject to premarket approval requirements. At MIMEDX, the products affected by this policy include AMNIOFIX® INJECTABLE, EPIFIX® MICRONIZED, and AMNIOFILL® brands. Our most requested and used flagship brands: EPIFIX, EPICORD®, AMNIOFIX, and AMNIOCORD® are **not** impacted by the FDA enforcement discretion.

The FDA provided a period of enforcement discretion – a sufficient window of notification with respect to the Investigational New Drug (IND) and premarket approval requirements – in order to give all manufacturers time to assess what steps to take and prepare and submit to FDA any appropriate application (e.g., IND or Biologics License Application), which may be required. On April 21, 2021, the FDA issued a follow-up statement reaffirming that May 31, 2021 was the close of this enforcement discretion period; this announcement can be found here[1].

The FDA made it clear that its guidance applies to **all** HCT/P product manufacturers and indicated it would take action against any company not in compliance. Additionally, the FDA stated companies must either have an IND in effect or an approved biologics license, and that products could not be lawfully marketed without a specific approval pathway or indication. MIMEDX has confirmed with the FDA that only products with premarket approval, an approved biologics license in this case, should be commercially available after May 31, 2021. Products only having an IND “on file,” cannot be

[11] https://www.fda.gov/news-events/fda-voices/advancing-development-safe-and-effective-regenerative-medicine-products?utm_medium=email&utm_source=govdelivery

commercially sold or marketed outside of the approved IND clinical trial process. **MIMEDX is in compliance with these guidelines**.

MIMEDX MOVES TO ADVANCE REGENERATIVE MEDICINE:

From the first FDA notice in 2017, MIMEDX has taken multiple actions to comply with these standards. To that end, I am pleased to share these highlights on the progress made:

- MIMEDX effectuated four IND programs to evaluate the safety and effectiveness of AMNIOFIX INJECTABLE (micronized dehydrated Human Amnion Chorion Membrane (mdHACM)) in the areas of Achilles Tendonitis, Chronic Cutaneous Ulcers, Plantar Fasciitis and Knee Osteoarthritis. Each of these INDs is considered to be in effect and in compliance with FDA directives. Here are some recent milestones that ensure continuity of care and advance category science:
    - Completed enrollment and last patients' final clinical visits in our Phase 3 IND study of AMNIOFIX INJECTABLE as a potential treatment for Achilles Tendonitis
    - Completed enrollment and last patients' final clinical visits in our Phase 3 IND study of AMNIOFIX INJECTABLE as a potential treatment for Plantar Fasciitis
    - Completed enrollment and all clinical effectiveness endpoint visits in a Phase 2B IND study of AMNIOFIX INJECTABLE as a potential treatment for Knee Osteoarthritis
    - Received notification from the FDA that the Company's IND for the use of AMINIOFIX INJECTABLE in Chronic Cutaneous Ulcers was allowed to proceed.

As a result of these prompt efforts, I can share these milestones:

- The Company received Regenerative Medicine Advanced Therapy (RMAT) designation for AMNIOFIX INJECTABLE for the treatment of Knee Osteoarthritis
- The Company has taken steps to enhance our Chemistry, Manufacturing and Controls, and transition our manufacturing facilities to Current Good Manufacturing Practices (CGMP) standards
- We assembled a leadership team with extensive development, regulatory and registration expertise needed to advance the rigor of placenta-based science and accelerate the transition of our category to align with recent FDA guidance.

COMMITMENT TO YOU:

We support FDA policies and believe that the entire industry must rise to the highest standards. As a pioneer utilizing amniotic tissue as a platform for regenerative medicine, MIMEDX made significant investments in each of the requirements that must be met for BLA approval. This is an opportunity to support scientific rigor, provide clinical evidence and demonstrate how these innovative technologies advance human health.

While this presents a change in the product offerings you have available from MIMEDX, our most requested and used flagship brands, EPIFIX, EPICORD, AMNIOFIX, and AMNIOCORD, are not impacted

by the ending of the FDA enforcement discretion period. We will continue to work with the FDA to recommend pathways so that you and your patients can access products to address pressing health needs.

We will keep you up to date on the specific details regarding the Company's logistics, the timing of our transition plans and our adherence efforts toward the end of the enforcement discretion period. Our field personnel, customer service support staff, headquarters employees and medical team will continue to dedicate their efforts to what matters most to you – quality products, information, education and outstanding service.

At MIMEDX, our mission is to improve people's health and lives through innovation that makes healing possible. By advancing category science and increasing access to evidence-based regenerative technologies, we demonstrate commitment to you and your patients.

If you have any questions, please feel free to email me directly at twright@mimedx.com, or reach me by phone at 678-695-5146. I welcome your questions and thoughts.

Best wishes,

Timothy R. Wright
Chief Executive Officer