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): September 21, 2020

MIMEDX GROUP, INC.
(Exact name of registrant as specified in charter)

Florida	**001-35887**	**26-2792552**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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
None	**n/a**	**n/a**

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 Disclosure

On September 21, 2020, MiMedx Group, Inc. (the "***Company***" or the "***Registrant***") announced the conclusion of enrollment into its Phase 2B study of its micronized injectable amniotic tissue product in patients with osteoarthritis (OA) of the knee (KOA). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All information in the press release speaks as of the date thereof, and MiMedx does not assume any obligation to update such information in the future. In addition, MiMedx disclaims any inference regarding the materiality of such information which otherwise may arise as a result of its furnishing such information under Item 7.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated September 21, 2020.
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: September 21, 2020

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

Exhibit 99.1

MiMedx Concludes Enrollment for Phase 2B Study of Osteoarthritis (OA) of the Knee

Research Advances Understanding of Amniotic Tissue as Potential Unique Treatment for Painful Chronic Condition that Affects 242 Million People Globally

MARIETTA, Ga., September 21, 2020 — MiMedx Group, Inc. (OTC PINK: MDXG) ("MiMedx" or "the Company"), an industry leader in advanced wound care and a therapeutic biologics company, announced the conclusion of enrollment into its Phase 2B study of its micronized injectable amniotic tissue product in patients with osteoarthritis (OA) of the knee (KOA).

"Osteoarthritis is by far the most common joint disease – millions of adults experience pain and decreased quality of life every day because of joint destruction caused by osteoarthritis," said Alfred Gellhorn, MD, Associate Professor of Clinical Rehabilitation and Director of Sports Medicine, Weill Cornell Medical Center. "Although knee replacement is an option for those with advanced knee arthritis, this should be reserved for end-stage disease; it is extremely expensive and carries significant potential risks. We are in desperate need of better conservative options to treat those with mild-to-moderate knee arthritis. Current treatments, including oral anti-inflammatory medications, cortisone injections, and hyaluronic acid injections, are very limited in the amount of relief they provide. Furthermore, anti-inflammatories have negative cardiovascular effects and injected steroids cause further joint degeneration. In my practice, patients are frustrated with these limited options and very interested in novel approaches that provide safe and long-lasting pain reduction. I believe this Phase 2B clinical trial is critically important to inform the potential for MiMedx's amniotic membrane-based technology to fill this treatment void."

The OA Clinical Trial is the first randomized clinical study of a micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) Injection in the Treatment of KOA. A previously published retrospective study by Dr. Gellhorn provided initial evidence of pain reduction and functional improvement in a cohort of 40 patients with chronic tendinopathy and arthropathy. The subsequent publication of an observational study by Kris Alden, M.D., Ph.D., Orthopaedic Surgeon, Hinsdale Orthopaedics, of 100 knee injections in 82 KOA patients provided further evidence that mdHACM injections reduced pain and improved function. In both studies, pain and functional improvements continued to improve over the entire observation period, and no significant adverse events were noted.

MiMedx Executive Vice President, Research and Development, Robert Stein, M.D., Ph.D., commented, "We have enrolled the planned number of patients needed to assess the statistical significance of response to treatment in this Phase 2B trial, ahead of our enrollment schedule, despite the access restrictions from the COVID-19 pandemic. We are grateful to our dedicated investigators and their staff for making this possible. If our data analyses support product safety and effectiveness, we will approach the FDA and leverage our Regenerative Medicine Advanced Therapy (RMAT) designation to discuss our pivotal study plans and advance the program toward a Biologics License Application (BLA) filing."

“Osteoarthritis is responsible for a staggering public health and economic impact: more than 242 million people worldwide currently suffer from symptomatic OA of the knee and hip; 45% of all people have a lifetime risk of developing OA of the knee; and OA is responsible for $71 billion in lost earnings annually in the U.S.,” said Timothy R. Wright, Chief Executive Officer, MiMedx. “Addressing this significant, unmet patient need is urgent – and MiMedx is committed to applying our unique amniotic tissue platform to better understand and address both the symptomatic pain and underlying loss of function caused by OA of the knee. We look forward to sharing these data.”

About MiMedx OA Trial

This trial is a Phase 2B, prospective, double-blinded, randomized controlled trial of the micronized dehydrated Human Amnion Chorion Membrane (mdHACM) injection as compared to saline placebo injection in the treatment of osteoarthritis of the knee. Trial enrollment was planned to include 466 patients between the ages of 21 to 80 years, with a diagnosis of osteoarthritis defined as grade 1 to 3 on the Kellgren Lawrence grading scale and a Visual Analog Scale (VAS) for Pain score greater than 45. Due to a lower than expected number of study participant dropouts, and with an adequate number of patients meeting the required time in study to assess the primary endpoint, the final number randomized will be in the range of 430-440.

The primary efficacy endpoints include change from baseline in VAS at 90 days, change from baseline in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at 90 days, and incidence of related Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Adverse Events at 365 days. Secondary endpoints include, change from baseline in VAS at 180 days and change from baseline in WOMAC at 180 days. The WOMAC Index has become a standard study metric in KOA studies, and its use has been extensively validated.

Important Cautionary Statement

This press release may include forward-looking statements. 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. There can be no assurance that the clinical study will be successful, will be completed on time, or result in an approved Biologics License Application or future products or indications. 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 press release and the Company assumes no obligation to update any forward-looking statement.

About MiMedx

MiMedx® is an industry leader in advanced wound care and a therapeutic biologics company developing and distributing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare. The Company processes the human placental tissue utilizing its proprietary PURION® process methodology, among other processes, to produce allografts by employing aseptic processing techniques in addition to terminal sterilization. MiMedx has supplied more than 1.9 million allografts to date. For additional information, please visit www.mimedx.com.

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