UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934**

Date of Report (date of earliest event reported): September 5, 2013

# MIMEDX GROUP, INC.

(Exact name of registrant as specified in charter)

| **Florida** | **000-52491** | **26-2792552** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **1775 West Oak Commons Ct. NE**<br>**Marietta, GA**<br>(Address of principal executive offices) | **30062**<br>**(Zip Code)** |
|---|---|

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01 Other Events**

On September 4, 2013, MiMedx Group, Inc., (the "Company") issued a press release addressing a letter received from the Food and Drug Administration (FDA) and reiterating its 2013 and 2014 guidance. Specifically, the Company stated its disagreement with the FDA letter, and indicated it does not expect the letter to impact its expected revenue range for 2013 of $54 million to $60 million or its 2014 goal of $90 million to $110 million.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits**

(c) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | MiMedx Group, Inc. Press Release, dated September 4, 2013 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**MIMEDX GROUP, INC.**

Dated: September 5, 2013

By: /s/: Michael J. Senken
Michael J. Senken, Chief Financial Officer

**Exhibit 99.1**

**PRESS RELEASE Contact: Michael Senken**
**Phone: (770) 651-9100**

**MARIETTA, Georgia, September 4, 2013** (PR Newswire) – MiMedx Group, Inc. (NASDAQ: MDXG), an integrated developer, manufacturer and marketer of patent protected regenerative biomaterials and bioimplants processed from human amniotic membrane, confirmed today that it is in receipt of an "Untitled Letter" from the Food and Drug Administration ("FDA"). The Company further announced that it expressly disagrees with the position in the letter and has been in conversation with the FDA to resolve the matter as quickly as possible. The letter questions the Company's Amnion / Chorion Injectable products' eligibility for marketing solely under Section 361 of the Public Health Service Act.

As explained on the FDA's website, an "Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of regulatory significance for a Warning Letter."

Bill Taylor, the Company's President and COO, commented, "The Company was surprised by this letter considering the FDA conducted a directed inspection of our facility in July 2012, one of the express purposes of which was to 'determine the status of the [Company's] AmnioFix® injectable product.' The inspection report indicated that 'information regarding the [Company's] AmnioFix® Injectable product, which was rolled out August 2011, was collected and forwarded to CBER for review. The information collected included advertising, packaging, process procedures and studies conducted related to the product.' Following that inspection, the inspector advised us that CBER had completed its review and had no findings or further questions and, therefore, the inspection was classified as NAI, or No Action Indicated. The formal establishment inspection report confirming the NAI conclusion was issued on December 4, 2012." The establishment report is posted on the Company's website at www.mimedx.com.

MiMedx is very focused on regulatory compliance and proceeded with marketing the injectable product only after receiving advice from outside legal counsel that the product met the criteria for regulation as an HCT/P under Section 361 of the Public Health Service Act. The Company believes the FDA's conclusion is based on a misunderstanding of the micronization process and is responding to the Untitled Letter and will reiterate its request for a meeting with the FDA.

The Company reiterated its expected revenue range for 2013 of $54 million to $60 million and its 2014 goal of $90 million to $110 million. The revenues from the Company's injectable are projected to be approximately 15% of the Company's 2014 revenues.

Parker H. "Pete" Petit, the Company's Chairman & CEO, stated, "Based on other precedents, the Company believes it should be able to continue to sell its injectable products, but even if that not the case, management believes it can refocus its resources to achieve its stated revenue goals."

**About the Company**
MiMedx® is an integrated developer, manufacturer and marketer of patent protected regenerative biomaterial products and bioimplants processed from human amniotic membrane. "***Innovations in Regenerative Biomaterials"*** is the framework behind our mission to give physicians products and tissues to help the body heal itself. Our biomaterial platform technologies include the device technologies HydroFix® and CollaFix™, and our tissue technologies, AmnioFix® and EpiFix®. Our tissue technologies are processed from human amniotic membrane that is derived from the donated placentas. Through our donor program, mothers delivering full-term Caesarean section births can elect in advance of delivery to donate the placenta in lieu of having it discarded as medical waste. We process the human amniotic membrane utilizing our proprietary Purion® Process, to produce a safe, effective and minimally manipulated implant for homologous use. MiMedx® is the leading supplier of amniotic tissue, having supplied over 170,000 allografts to date to distributors and OEMs for application in the Wound Care, Surgical, Sports Medicine, Ophthalmic and Dental sectors of healthcare.

**Safe Harbor Statement**
This press release includes statements that look forward in time or that express management's beliefs, expectations or hopes. Such statements are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to the resolution of the FDA's concerns and the timing thereof, the Company's belief that the FDA's conclusion is based on a misunderstanding of the Company's micronization process, whether the Company will be able to continue to sell its injectable product or refocus its resources and the Company's achievement of its revenue goals for 2013 and 2014. These statements are based on current information and belief, and are not guarantees of future performance. Among the risks and uncertainties that could cause actual results to differ materially from those indicated by such forward-looking statements include that the issues raised in the FDA letter are not timely or favorably resolved, that the Company is unable to sell its injectable product or to refocus its resources, that the Company may not meet its revenue goals for 2013 and 2014, and the risk factors detailed from time to time in the Company's periodic Securities and Exchange Commission filings, including, without limitation, its 10-K filing for the fiscal year ended December 31, 2012. By making these forward-looking statements, the Company does not undertake to update them in any manner except as may be required by the Company's disclosure obligations in filings it makes with the Securities and Exchange Commission under the federal securities laws.