

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): December 30, 2014

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**

(Address of principal executive offices)

30062

(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:

- 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))

The information provided pursuant to Items 2.02 and 7.01 of this 8-K is to be considered “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 2.02. Results of Operations and Financial Condition

On December 30, 2014, MiMedx Group, Inc. (the “Company”) issued a press release, which among other things, included information regarding the Company's 4th quarter and full-year 2014 financial performance. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure

Conference Call

On January 2, 2015, at 10:30am EST, the Company will host a live broadcast of its conference call with shareholders to present prepared remarks and respond to questions about recent events. A listen-only simulcast of the conference call will be available on-line at the Company's website at www.mimedx.com. A 30-day on-line replay will be available approximately one hour following the conclusion of the live broadcast. The replay can also be found on the Company's website at www.mimedx.com.

Share Repurchase Plan

As previously announced, on May 12, 2014, the Company's Board of Directors authorized the repurchase of up to \$10 million of Company common stock from time to time, through December 31, 2014. The Board of Directors has now extended this share repurchase program through December 31, 2015. All other terms remain the same. As of December 31, 2014, of the \$10 million authorized, the Company has \$4,416,322 remaining to be spent under the program. The timing and amount of additional repurchases, if any, will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	MiMedx Group, Inc. Press Release dated December 30, 2014

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: December 31, 2014

By:

/s/ Michael J. Senken

Michael J. Senken, Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1

MiMedx Group, Inc. Press Release dated December 30, 2014

MIMEDX COMMENTS ON RECENT FDA DRAFT GUIDANCE ON MINIMAL MANIPULATION OF HCT/Ps

COMPANY REPORTS THAT ITS 4TH QUARTER AND FULL YEAR 2014 REVENUES WILL EXCEED UPPER END OF FORECAST

Marietta, Georgia, December 30, 2014, (PR Newswire) -- MiMedx Group, Inc. (NASDAQ: MDXG), the leading regenerative medicine company utilizing human amniotic tissue and patent-protected processes to develop and market advanced products and therapies for the Wound Care, Surgical, Orthopedic, Spinal, Sports Medicine, Ophthalmic and Dental sectors of healthcare, commented on the Draft Guidance for Industry on Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (“HCT/Ps”) that the Food and Drug Administration (“FDA”) published for comment on December 23, 2014.

Parker H. “Pete” Petit, Chairman and CEO, stated, “MiMedx is pleased that the FDA has decided to engage industry participants and others in shaping the future of regulation of HCT/Ps. We believe we have much to contribute to this topic and welcome the opportunity to provide our comments.”

Bill Taylor, President and COO, added, “It is evident to us that FDA’s view on minimal manipulation has evolved since its prior public statements on the subject. It is also obvious that the agency began selective enforcement of this evolved view some sixteen months ago when it issued MiMedx an Untitled Letter without first having vetted its new position through any public process. This is fundamentally unfair. Other members of industry who have products that may be impacted by this guidance when it is finalized have been given notice and an opportunity to comment on the draft guidance prior to its application to them, whereas MiMedx had no such benefit prior to FDA taking the action that it did with respect to our micronized products in August 2013. There are at least nine other companies with competitive products that appear to be impacted by this draft guidance. To our knowledge, none of these companies have been asked to take their products off the market, and all of these companies will have time to comment, make transition plans, and take other actions they deem necessary under the circumstances.”

Petit continued, “Positions taken by FDA in the Untitled Letter issued to MiMedx in August 2013 with respect to our micronized products represent significant departures from long-standing precedents on which industry has justifiably relied. This action was taken with no systematic input from the scientific and medical experts in the field or industry participants. Although we appreciate the prospect of an open forum, we do not believe the issuance of draft guidance on which comments may be submitted is an adequate substitute for the public process that should support such a sweeping change in the longstanding interpretation of agency regulations. We intend to urge the FDA to consider a more robust process and formal transition period for industry to come into compliance with any new requirements, similar to the approach FDA took with respect to Laboratory Developed Tests.”

Petit added, “It is a fundamental principle of administrative law that federal agencies must treat similarly situated parties similarly. As disclosed in our quarterly report on Form 10-Q, the Company has asked the FDA to consider alternative formulations of a particulate product to replace its current micronized product. We were prepared to submit a plan to discontinue sales of the current form of our micronized products. In light of the December 23, 2014, Draft Guidance and the agency’s apparent willingness to let similar products remain on the market pending completion of the guidance review process, we have proposed to FDA that we continue to sell our current micronized products until we have been afforded an opportunity to participate in the full guidance document review, the Draft Guidance is finalized and similarly situated competitors are required to comply.”

Petit concluded, “We want to be treated the same as other industry participants. Also, as previously stated, our announced 2015 forecast for revenue to range from \$175 million to \$190 million is not dependent on our ability to continue to market a micronized product. Nor do we expect the Draft Guidance to impact our ability to achieve the forecasted revenues. In addition, I am pleased to advise shareholders that we will exceed the upper end of our revenue guidance for both the 4th quarter and full year 2014. We will provide further details in a press release on January 12, 2014, prior to the J.P. Morgan Healthcare Conference. ”

About MiMedx

MiMedx® is an integrated developer, processor 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 AmnioFix® and EpiFix®, our tissue technologies processed from human amniotic membrane that is derived from donated placentas. Through our donor program, a mother delivering via full-term Caesarean section birth 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 and effective implant. MiMedx® is the leading supplier of amniotic tissue, having supplied over 300,000 allografts to date 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 prospect of a more robust process and formal transition period, whether MiMedx may continue to sell its current micronized products and the Company’s revenue expectations for 4th quarter and full year 2014 and full year 2015. 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 FDA may not agree to a more robust process and formal transition period, MiMedx may be forced to discontinue sales of its current micronized products and may not achieve its revenue expectations, 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, 2013, and the most recent Form 10-Q. 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.