

**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 of 1934

Date of Report (date of earliest event reported): June 22, 2017



Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Utah
(State or other jurisdiction of
incorporation or organization)

0-18592
(Commission
File Number)

87-0447695
(I.R.S. Employer
Identification No.)

1600 West Merit Parkway
South Jordan, Utah
(Address of principal executive offices)

84095
(Zip Code)

(801) 253-1600
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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:

- 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))

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 June 22, 2017, Merit Medical Systems, Inc. (the "Company") issued a press release announcing that it has received 513(f)(2) (de novo) classification from the U.S. Food & Drug Administration to expand the indication of the Company's Embosphere® Microspheres to include prostatic artery embolization for symptomatic benign prostatic hyperplasia.

The information in this Current Report on Form 8-K (including the exhibit attached hereto) is intended to be furnished and 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 it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

- 99.1 Press Release, dated June 22, 2017, entitled "Merit Medical's Embosphere® Microspheres Receive FDA 513(f)(2) (de novo) Classification for Prostatic Artery Embolization Indication".

SIGNATURES

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

MERIT MEDICAL SYSTEMS, INC.

Date: June 22, 2017

By: /s/ Brian G. Lloyd
Brian G. Lloyd
Chief Legal Officer and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
99.1	Press Release, dated June 22, 2017, entitled "Merit Medical's Embosphere® Microspheres Receive FDA 513(f) (2) (de novo) Classification for Prostatic Artery Embolization Indication".



PRESS RELEASE

1600 West Merit Parkway,
South Jordan, Utah 84095
Telephone +1 801.253.1600
Fax +1 801.253.1688

FOR IMMEDIATE RELEASE

Date: June 22, 2017
Contact: Anne-Marie Wright, Vice President, Corporate Communications
Phone: (801) 208-4167 e-mail: awright@merit.com Fax: (801) 253-1688

Merit Medical's Embosphere® Microspheres Receive FDA 513(f)(2) (de novo) Classification for Prostatic Artery Embolization Indication

SOUTH JORDAN, Utah - Merit Medical Systems, Inc. (NASDAQ:MMSI), a leading manufacturer and marketer of proprietary disposable devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology and endoscopy, today announced that it has received 513(f)(2) (de novo) classification from the FDA to expand indication for Merit's Embosphere® Microspheres. The indication now includes prostatic artery embolization (PAE) for symptomatic benign prostatic hyperplasia (BPH).

"Merit's Embosphere is the first embolic agent to receive FDA 513(f)(2) classification for prostatic artery embolization, providing a non-surgical treatment option for millions of men who suffer from BPH," said Fred P. Lampropoulos, Merit's Chairman and Chief Executive Officer.

BPH is an enlarged prostatic gland and can cause lower urinary tract symptoms for more than half of all men in their 60s and as many as 90% of men over age 70.1 The PAE procedure is performed through a tiny incision in the patient's upper thigh or wrist, and uses Embosphere Microspheres to occlude the prostatic arteries, reducing their blood supply and causing the prostate to shrink and improve symptoms.

ABOUT MERIT

Founded in 1987, Merit Medical Systems, Inc. is engaged in the development, manufacture and distribution of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force totaling approximately 290 individuals. Merit employs approximately 4,500 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; San Jose, California; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Tijuana, Mexico; Joinville, Brazil; Markham, Ontario, Canada; Melbourne, Australia; Tokyo, Japan; and Singapore.

FORWARD-LOOKING STATEMENTS

Statements contained in this release which are not purely historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties such as those described in Merit's Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent filings with the Securities and Exchange Commission. Such risks and uncertainties include risks relating to Merit's potential inability to

successfully manage growth through acquisitions, including the inability to commercialize technology acquired through completed, proposed or future transactions; product recalls and product liability claims; expenditures relating to research, development, testing and regulatory approval or clearance of Merit's products and risks that such products may not be developed successfully or approved for commercial use; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit; reforms to the 510(k) process administered by the U.S. Food and Drug Administration; restrictions on Merit's liquidity or business operations resulting from its current debt agreements; infringement of Merit's technology or the assertion that Merit's technology infringes the rights of other parties; the potential of fines, penalties or other adverse consequences if Merit's employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; laws and regulations targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in governing regulations; changes in tax laws and regulations in the United States or other countries; increases in the prices of commodity components; negative changes in economic and industry conditions in the United States or other countries; termination or interruption of relationships with Merit's suppliers, or failure of such suppliers to perform; fluctuations in exchange rates; concentration of a substantial portion of Merit's revenues among a few products and procedures; development of new products and technology that could render Merit's existing products obsolete; market acceptance of new products; volatility in the market price of Merit's common stock; modification or limitation of governmental or private insurance reimbursement policies; changes in healthcare policies or markets related to healthcare reform initiatives; failure to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; introduction of products in a timely fashion; price and product competition; availability of labor and materials; and fluctuations in and obsolescence of inventory. All subsequent forward-looking statements attributable to Merit or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Actual results will likely differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and Merit assumes no obligation to update or disclose revisions to those estimates.

REFERENCES

1. McWilliams, J. P., Kuo, M. D., Rose, S.C., Bagla, S., Caplin, D. M., Cohen, E. I., Faintuch, S., Spies, J. B., Saad, W. E., Nikolic, B. (2014). Society of Interventional Radiology position statement: prostate artery embolization for treatment of benign disease of the prostate. *Journal of Vascular and Interventional Radiology*, 25: 1349-1351. <http://dx.doi.org/10.1016/j.jvir.2014.05.005>
http://www.scvir.org/clinical/cpg/SIR_Pos_Statmt_PAE_Benign_dis_Prostate.pdf