# 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): November 22, 2019

# Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

| **Utah** | **0-18592** | **87-0447695** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| **1600 West Merit Parkway**<br>**South Jordan, Utah** | **84095** |
|---|---|
| (Address of principal executive offices) | (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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, no par value | MMSI | NASDAQ Global Select Market System |

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 November 21, 2019, Merit Medical Systems, Inc. (the "Company") issued a press release announcing that it had received FDA Breakthrough Device Designation for its WRAPSODY™ Endovascular Stent Graft System. A copy of the press release is furnished herewith as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibit

99.1 Press Release, dated November 21, 2019, entitled "Merit Medical Receives FDA Breakthrough Device Designation for WRAPSODY™ Endovascular Stent Graft System."

The information in this filing (including the exhibit furnished herewith) is furnished pursuant to General Instruction B.2. of Form 8-K and shall not be deemed to be "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.

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 99.1 | Press Release, dated November 21, 2019, entitled "Merit Medical Receives FDA Breakthrough Device Designation for WRAPSODY™ Endovascular Stent Graft System." |
| 104 | Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document |

**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: November 21, 2019

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


**FOR IMMEDIATE RELEASE**

**Date:** November 21, 2019
**Contact:** Anne-Marie Wright, Vice President, Corporate Communications
**Phone:** (801) 208-4167 e-mail: awright@merit.com Fax: (801) 253-1688

# MERIT MEDICAL RECEIVES FDA BREAKTHROUGH DEVICE DESIGNATION FOR WRAPSODY™ ENDOVASCULAR STENT GRAFT SYSTEM

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, oncology, critical care and endoscopy, announced today that it has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) for the Merit WRAPSODY™ Endovascular Stent Graft System. The WRAPSODY system is a flexible, self-expanding endoprosthesis for which Merit intends to seek indication for use in hemodialysis patients for the treatment of stenosis within the central veins of the outflow circuit of an arteriovenous fistula (AVF) up to the superior vena cava.

The FDA Breakthrough Devices Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA provides priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions. The WRAPSODY system is nearing completion of its "First in Man" studies, and is not currently available for sale.

"We are pleased with the recognition by the FDA of this worthwhile technology as well as the efforts of many members of our R&D team to bring the project to this point," said Fred P. Lampropoulos, Merit Medical's Chairman and CEO. "Most importantly, we believe this system will provide substantial benefits to patients who may utilize the system in the future."

## 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, oncology, critical care and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force and clinical support team totaling in excess of 300 individuals. Merit employs approximately 6,350 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; Aliso Viejo, California; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Tijuana, Mexico; Joinville, Brazil; Markham, Ontario, Canada; Melbourne, Australia; Tokyo, Japan; Reading, United Kingdom; Johannesburg, South Africa; and Singapore.

**FORWARD-LOOKING STATEMENTS**

Statements contained in this release which are not purely historical, including, without limitation, statements regarding the development, introduction or commercialization of new products, 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, 2018 and subsequent filings with the Securities and Exchange Commission. Such risks and uncertainties include inherent risks and uncertainties relating to Merit's potential inability to successfully commercialize technology developed internally or acquired through completed, proposed or future transactions; 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; infringement of Merit's technology or the assertion that Merit's technology infringes the rights of other parties; product recalls and product liability claims; changes in customer purchasing patterns or the mix of products Merit sells; risks and uncertainties associated with Merit's information technology systems, including the potential for breaches of security and evolving regulations regarding privacy and data protection; the pending exit of the United Kingdom from the European Union and uncertainties about when, how or if such exit will occur; potential for significant adverse changes in governing regulations, including reforms to the procedures for approval or clearance of Merit's products by the U.S. Food & Drug Administration or comparable regulatory authorities in other jurisdictions; 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; development of new products and technology that could render Merit's existing or future products obsolete; market acceptance of new products; modification or limitation of governmental or private insurance reimbursement policies; changes in healthcare policies or markets related to healthcare reform initiatives; 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; fluctuations in and obsolescence of inventory; and other factors referred to in Merit's Annual Report on Form 10-K for the year ended December 31, 2018 and other materials filed with the Securities and Exchange Commission. 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.

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