

**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 17, 2019



**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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 June 17, 2019, Merit Medical Systems, Inc., a Utah corporation (the “Merit”), issued a press release, entitled “Merit Medical Acquires Brightwater Medical, Inc.” related to the acquisition by Merit of Brightwater Medical, Inc, a copy of which is filed as Exhibit 99.1 to this Current Report.

The information contained in this Item 7.01 and in the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for purposes of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is not deemed incorporated by reference by any general statements incorporating by reference this Current Report or future filings into any filings under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that Merit specifically incorporates the information by reference. By filing this Current Report and furnishing this information, Merit makes no admission or statement as to the materiality of any information in this Current Report that is required to be disclosed solely by reason of Regulation FD.

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

(d) Exhibits

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION</u>
99.1	Press release issued by Merit Medical Systems, Inc., dated June 17, 2019, entitled “Merit Medical Acquires Brightwater Medical, Inc.”

## 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 20, 2019

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

## EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
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## 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 17, 2019  
**Contact:** Anne-Marie Wright, Vice President, Corporate Communications  
**Phone:** (801) 208-4167 e-mail: [awright@merit.com](mailto:awright@merit.com) Fax: (801) 253-1688

**MERIT MEDICAL ACQUIRES  
BRIGHTWATER MEDICAL, INC.**

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 acquired Brightwater Medical, Inc., based in Temecula, California. The transaction consists of a \$35 million upfront payment and potential earn-out payments of up to \$15 million based on receipt of CE mark approval and achievement of future sales targets.

Brightwater Medical was founded by Dr. Robert Smouse, Professor of Radiology and Surgery, University of Illinois College of Medicine. Its primary product, the ConvertX®, is a single device used to replace a series of devices and procedures used to treat severe obstructions of the ureter. The system is designed to be implanted once and converted from a nephroureteral catheter to a nephroureteral stent without requiring sedation or local anesthesia. Brightwater Medical recently received FDA clearance for the ConvertX® biliary stent system.

“The ConvertX® system is designed to reduce multiple visits to the hospital, saving patients the risk and discomfort of a second interventional procedure while allowing additional utilization of facilities,” said Fred P. Lampropoulos, Chairman and CEO of Merit Medical. “The ConvertX® system complements Merit’s Resolve™ drainage catheter portfolio and potentially drives pull-through of other Merit products such as InQwire™ guide wires, Advocate™ PTA balloons and other vascular products.”

Over the next several months, Merit Medical intends to maintain Brightwater Medical’s production capabilities in Temecula while duplicating those capabilities in its catheter facility in Pearland, Texas, prior to transferring the ConvertX® manufacturing operations to its Pearland facility. Merit Medical’s management estimates that the transaction will be approximately \$(0.05) decreitive to earnings per share for the year ending December 31, 2019 on

a GAAP basis and approximately \$(0.03) decrease to earnings per share for the year ending December 31, 2019 on a non-GAAP basis due to deal-related expenses, severance, transfer and integration costs, and international regulatory expenses. Management's current revenue expectations for the ConvertX® product for calendar year 2019 are approximately \$1 million with expectations of growth to approximately \$25 million in the fifth full year of sales. Upon transfer of the ConvertX® manufacturing operations to Merit's Pearland facility, management believes non-GAAP gross margins in the 70-75% range are attainable.

Brightwater Medical currently has approximately 40 U.S. accounts serviced by two direct sales representatives and a small number of distributors.

"We believe our ability to align this product with our existing sales force calling on interventional radiologists, as well as growth in markets outside the United States will allow for future growth," Lampropoulos said.

### **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 6,300 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; San Jose and 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 Merit's forecasted plans, revenues, earnings per share, gross margins or other financial results (on a GAAP or non-GAAP basis) or anticipated or completed acquisitions, 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 the following: Merit's potential inability to successfully manage the integration of Brightwater Medical and achieve anticipated financial results, product development, manufacturing efficiencies or other anticipated benefits; uncertainties as to whether Merit will achieve sales, gross margin, earnings and other results from the Brightwater Medical acquisition which are comparable to the experience or projections of Brightwater Medical; unknown costs and risks associated with the business and operations of Brightwater Medical; Merit's internal models or the projections referenced in this release; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit or the business and operations conducted by Brightwater Medical; how the occurrence of any unanticipated

event or cost in connection with the acquisition or integration of Brightwater Medical may affect Merit's compliance with its debt agreements; infringement of Merit's technology or the assertion that Merit's or Bridgewater Medical'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 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; the pending exit of the United Kingdom from the European Union and uncertainties about when, how or if such exit will occur; laws and regulations targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in governing regulations, including reforms to the procedures for approval or clearance of Merit's or Brightwater Medical's products by the U.S. Food & Drug Administration or comparable regulatory authorities in other jurisdictions; 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 or Brightwater Medical's suppliers, or failure of such suppliers to perform; fluctuations in exchange rates; uncertainties relating to the LIBOR calculation method and the potential phasing out of LIBOR; 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 or Brightwater Medical's products obsolete; market acceptance of new or acquired 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; 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.

#### NON-GAAP FINANCIAL MEASURES

Although Merit's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), Merit's management believes that certain non-GAAP financial measures referred to in this release provide investors with useful information regarding the underlying business trends and performance of Merit's ongoing operations and can be useful for period-over-period comparisons of such operations. Non-GAAP financial measures used in this release include:

- non-GAAP earnings per share; and
- non-GAAP gross margin.



Merit's management team uses these non-GAAP financial measures to evaluate Merit's profitability and efficiency, to compare operating results to prior periods, to evaluate changes in the operating results of its operating segments, and to measure and allocate financial resources internally. However, Merit's management does not consider such non-GAAP measures in isolation or as an alternative to such measures determined in accordance with GAAP.

Readers should consider non-GAAP measures used in this release in addition to, not as a substitute for, financial reporting measures prepared in accordance with GAAP. These non-GAAP financial measures generally exclude some, but not all, items that may affect Merit's net income. In addition, they are subject to inherent limitations as they reflect the exercise of judgment by management about which items are excluded. Merit believes it is useful to exclude such items in the calculation of non-GAAP earnings per share and non-GAAP gross margin because such amounts in any specific period may not directly correlate to the underlying performance of Merit's business operations and can vary significantly between periods as a result of factors such as new acquisitions, non-cash expenses related to amortization of previously acquired tangible and intangible assets, unusual compensation expenses or expenses resulting from non-ordinary course litigation, governmental proceedings or changes in tax regulations. Merit may incur similar types of expenses in the future, and the non-GAAP financial information included in this release should not be viewed as a statement or indication that these types of expenses will not recur. Additionally, the non-GAAP financial measures used in this release may not be comparable with similarly titled measures of other companies. Merit urges investors and potential investors to review the explanations below addressing how its non-GAAP financial measures relate to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate Merit's business or results of operations.

#### Non-GAAP Net Income

Non-GAAP net income is calculated by adjusting GAAP net income for certain items which are deemed by Merit's management to be outside of core operations and vary in amount and frequency among periods, such as expenses related to new acquisitions, non-cash expenses related to amortization of acquired tangible and intangible assets, unusual compensation expenses or expenses resulting from non-ordinary course litigation, governmental proceedings or changes in tax regulations, as well as other items.

#### Non-GAAP Earnings Per Share

Non-GAAP earnings per share is defined as non-GAAP net income divided by the diluted shares outstanding for the corresponding period.

#### Non-GAAP Gross Margin

Non-GAAP gross margin is calculated by reducing GAAP cost of sales by amounts recorded for amortization of intangible assets and inventory mark-up related to acquisitions.

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