
**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): September 16, 2024



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

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 1.01. Entry into a Material Definitive Agreement.

On September 16, 2024, Merit Medical Systems, Inc., a Utah corporation (“Merit”), entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Cook Medical Holdings LLC, an Indiana limited liability company (“Cook Medical”), to purchase Cook Medical’s lead management portfolio of medical devices and certain related assets for total cash consideration of approximately \$210 million (collectively, the “Acquisition”). Merit expects to fund the Acquisition through a combination of cash on hand and borrowings under its long-term credit facility. The closing of the proposed Acquisition is expected to occur during the fourth quarter of 2024, subject to the receipt or waiver (in accordance with the provisions of the Purchase Agreement) of certain closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and other customary closing conditions. In connection with the projected closing of the Acquisition, Merit proposes to enter into a transition services agreement with Cook Medical, pursuant to which Cook Medical would provide manufacturing and other services to Merit during a two-year transition period.

The Purchase Agreement contains customary representations and warranties, as well as customary indemnification provisions and post-closing covenants. The representations and warranties are insured pursuant to a buyer-side representation and warranty insurance policy (the “RWI”), subject to standard exceptions and limitations, obtained by Merit in connection with the Acquisition. Recovery under the RWI is Merit’s sole recourse for breaches of representations and warranties, other than with respect to fraud.

The foregoing summary of the principal terms of the Purchase Agreement is not complete and is qualified in its entirety by the actual terms and conditions of the Purchase Agreement, a copy of which Merit intends to file in a future filing with the SEC. The representations, warranties, and other terms contained in the Purchase Agreement were made solely for the purposes of such agreement and as of specified dates, were solely for the benefit of the parties to the Purchase Agreement, and may be subject to limitations agreed upon by the contracting parties. Those representations and warranties may have been made for the purposes of allocating contractual risk between the parties to the Purchase Agreement instead of establishing these matters as facts, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors are not third-party beneficiaries under the Purchase Agreement and should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of Merit, Cook Medical, any of their respective subsidiaries or affiliates, or the assets or business that Merit proposes to acquire pursuant to the Acquisition. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts, since (i) they were made only as of the date of the Purchase Agreement or prior, specified dates, (ii) in some cases they are subject to qualifications with respect to materiality, knowledge and/or other matters, and (iii) they may be modified in important part by the underlying exhibits and schedules.

Item 2.02. Results of Operations and Financial Condition.

On September 17, 2024, Merit issued a press release announcing the Acquisition (the “Acquisition Press Release”) and updating its 2024 fiscal year financial guidance in light of the Acquisition. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this “Current Report”) and incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On September 16, 2024, Merit issued a press release announcing the six-month findings of its WRAPSODY™ Arteriovenous Access Efficacy (WAVE) pivotal trial. A copy of the press release is furnished as Exhibit 99.2 to this Current Report.

On September 17, 2024, Merit issued the Acquisition Press Release (Exhibit 99.1) announcing the Acquisition.

The information contained in Item 2.02 above and this Item 7.01 of this Current Report (including Exhibits 99.1 and 99.2 attached hereto) 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 Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by Merit under the Securities Act of 1933, as amended (the “Securities Act”), or the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

Merit is making reference to non-GAAP financial information in the Acquisition Press Release. A quantitative reconciliation of such non-GAAP financial information to comparable GAAP financial information is not available without unreasonable effort.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information included in this Current Report contains forward-looking statements about Merit that involve substantial risks and uncertainties. Merit intends such statements, and all subsequent forward-looking statements attributable to Merit, to be expressly qualified in their entirety by these cautionary statements and covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Exchange Act and Section 27A of the Securities Act. In some cases, forward-looking statements can be identified by the use of terminology such as “anticipate,” “believe,” “continue,” “estimate,” “expect,” “forecast,” “intend,” “may,” “might,” “plan,” “potential,” “project,” “will,” “would,” “seek,” “should,” “could,” “can,” “predict,” “potential,” “continue,” “objective” or other forms of these words or similar words or expressions, or the negative thereof or other comparable terminology. However, not all forward-looking statements contain such identifying words. All statements included in this Current Report, other than statements of historical fact, are forward-looking statements for purposes of the Exchange Act and the Securities Act, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or any assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. Additionally, forward-looking statements include, among other things, the expected timing of the closing of the Acquisition, the ability of Merit and Cook Medical to satisfy the closing conditions under the Purchase Agreement (including the execution of related agreements referenced in the Purchase Agreement), the receipt of required regulatory approvals, and the estimated or anticipated benefits of the Acquisition.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Merit’s actual results, levels of activity, performance or achievement to be materially different from those expressed or implied by these forward-looking statements, including those risks, uncertainties and other factors described in Merit’s Annual Report on Form 10-K for the year ended December 31, 2023 and Merit’s Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2024 and June 30, 2024, and subsequent filings with the SEC.

All forward-looking statements included in this Current Report speak only as of the date made, are based on information available to Merit as of such date, and are subject to change. Merit assumes no obligation to update or revise any forward-looking statement. If Merit does update or correct one or more forward-looking statements, readers should not conclude that Merit will make additional updates or corrections. Merit’s actual results will likely differ, and may differ materially, from anticipated results. Readers should not unduly rely on any such forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION</u>
99.1	Press Release, dated September 17, 2024, entitled “Merit Medical Signs Agreement to Purchase Lead Management Portfolio from Cook Medical”
99.2	Press Release, dated September 16, 2024, entitled “Merit Medical’s WRAPSODY WAVE Trial Demonstrates Superior Patency versus Standard of Care in AV Fistula Patients”
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: September 18, 2024

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

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Merit Medical Signs Agreement to Purchase Lead Management Portfolio from Cook Medical®

- *Asset acquisition of Cook Medical's end-to-end lead management product portfolio strengthens Merit's existing electrophysiology and CRM business*
- *Asset acquisition projected to add approximately \$40 million of revenue, on an annualized basis beginning in fiscal year 2025, with a solid growth profile serving an underpenetrated global lead management market*
- *Merit reaffirms full-year 2024 financial guidance previously issued on August 1, 2024, and updates full-year 2024 financial guidance to include the projected impact from this acquisition post-close*

SOUTH JORDAN, Utah, September 17, 2024 (GLOBE NEWSWIRE) -- Merit Medical Systems, Inc. (NASDAQ: MMSI), a global leader in healthcare technology, today announced it has signed a definitive asset purchase agreement to purchase Cook Medical's lead management portfolio for total cash consideration of approximately \$210 million. Merit expects to fund the transaction through a combination of cash on hand and borrowings under its long-term credit facility. The closing of the proposed transaction is expected to occur during the fourth quarter of 2024, subject to the receipt or waiver (in accordance with the provisions of the asset purchase agreement) of certain closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and other customary closing conditions.

Cook Medical's lead management business has 34 years of operating history and provides a comprehensive end-to-end product portfolio of medical devices and accessories used in lead management procedures for patients who need a pacemaker or an implantable cardioverter-defibrillator (ICD) lead removed or replaced.

"This transaction is consistent with our Continued Growth Initiatives (CGI) and positions Merit to offer clinicians an increasingly comprehensive set of solutions to support cardiac intervention patients, from diagnosis, to therapy and intervention, to post-procedure care," said Fred P. Lampropoulos, Merit's Chairman and Chief Executive Officer. "We believe this transaction will strengthen our fast-growing, high-margin electrophysiology and CRM business with the addition of differentiated products and an established commercial infrastructure. We believe the transaction will enhance our position in the cardiac intervention market, which we estimate represents an annual addressable opportunity of more than \$900 million in the US, EMEA and APAC regions. Specifically, beginning in fiscal year 2025, the addition of Cook's lead management business positions Merit to represent more than \$100 million in combined annualized electrophysiology and cardiac rhythm management revenue serving the global cardiac intervention market."

Mr. Lampropoulos continued: “We have updated our full-year 2024 financial guidance to include the projected impact of this acquisition from a prospective closing date of October 31, 2024 to December 31, 2024 and, importantly, we have reaffirmed our updated full-year 2024 financial guidance previously issued on August 1, 2024. While we anticipate the transaction will be modestly dilutive to our full-year 2024 non-GAAP profitability given the partial-year contribution, we believe the financial profile of this acquisition is very attractive and is consistent with our goal of delivering sustainable, constant currency growth, improving profitability and strong free cash flow generation. We look forward to discussing this acquisition and our updated outlook for 2024 on our third quarter earnings report on October 30, 2024.”

Non-GAAP net income; non-GAAP earnings per share; non-GAAP gross margin; non-GAAP operating margin and constant currency revenue are non-GAAP financial measures. A description of these financial measures is included under the heading “Non-GAAP Financial Measures” below. A quantitative reconciliation of such financial measures to comparable GAAP financial measures is not available without unreasonable effort.

Financial Summary:

Merit believes that the assets it proposes to acquire from Cook Medical generated approximately \$37 million of revenue over the twelve-month period ended December 31, 2023, with sales to customers in the US, EMEA, APAC and ROW representing approximately 41%, 42%, 11% and 6%, respectively. If the proposed transaction (including Merit’s proposed execution of a transition services agreement pursuant to which Cook Medical would provide manufacturing and other services to Merit during a two-year transition period) is consummated, of which there can be no assurance, the assets Merit proposes to acquire from Cook Medical, are projected to contribute revenue, from a projected closing date of October 31, 2024 through December 31, 2024, in the range of \$4 to \$6 million and are projected, during the same period of time, to dilute Merit’s previously forecasted non-GAAP operating margin, non-GAAP net income and non-GAAP earnings per share, inclusive of approximately \$1.8 million of lower interest income on cash balances used for the total purchase consideration and excluding approximately \$1.9 million of non-cash and non-recurring transaction-related expenses, and to be dilutive to Merit’s full-year 2024 GAAP net income and GAAP earnings per share. The acquisition is projected to be accretive to non-GAAP gross margin, accretive to non-GAAP operating margin in the first full-year post close, and accretive to non-GAAP net income and non-GAAP earnings per share in the second full-year post close. The acquisition, if completed, is projected to be dilutive to Merit’s GAAP net income and GAAP earnings per share in the first full-year post close, neutral in the second-full year post close and accretive thereafter.

Updated Fiscal Year 2024 Financial Guidance

Merit’s updated full-year 2024 financial guidance now reflects the projected impacts of the acquisition of Cook Medical’s lead management business from a projected closing date of October 31, 2024 through December 31, 2024. Merit is otherwise reaffirming prior full-year 2024 financial guidance previously announced on August 1, 2024.

Based upon the information currently available to Merit’s management, for the year ending December 31, 2024, after giving effect to the projected contribution of the assets proposed to be acquired from Cook Medical, assuming the proposed acquisition closes on October 31, 2024 and absent material acquisitions, non-recurring transactions or other factors beyond Merit’s current expectations, Merit now expects the following financial results:

Financial Measure	Updated Guidance ⁽¹⁾		Prior Guidance ⁽²⁾	
	Year Ending December 31, 2024	% Change Y/Y	Year Ending December 31, 2024	% Change Y/Y
Net Sales	\$1.339 - \$1.351 billion	6.5% - 7.5%	\$1.335 - \$1.345 billion	6% - 7%
Cardiovascular Segment	\$1.285 - \$1.295 billion	5.3% - 6.1%	\$1.281 - \$1.289 billion	5% - 6%
Endoscopy Segment	\$54 - \$56 million	45% - 52%	\$54 - \$56 million	45% - 52%
Non-GAAP				
Earnings Per Share	\$3.25 - \$3.34	14% - 17%	\$3.27 - \$3.35	15% - 17%

*Percentage figures approximated; dollar figures may not foot due to rounding

2024 Net Sales Guidance - % Change from Prior Year (Constant Currency) Reconciliation*

	Updated Guidance ⁽¹⁾		Prior Guidance ⁽²⁾	
	Low	High	Low	High
2024 Net Sales Guidance - % Change from Prior Year (GAAP)	6.5%	7.5%	6.2%	7.0%
Estimated impact of foreign currency exchange rate fluctuations	0.7%	0.7%	0.7%	0.7%
2024 Net Sales Guidance - % Change from Prior Year (Constant Currency)	7.2%	8.2%	6.9%	7.7%

*Percentage figures approximated and may not foot due to rounding

(1) "Updated Guidance" reflects Merit's full-year 2024 financial guidance, previously introduced on August 1, 2024, plus the projected impacts of the acquisition of assets from Cook Medical from a projected closing date of October 31, 2024 through December 31, 2024.

(2) "Prior Guidance" reflects Merit's full-year 2024 financial guidance, previously introduced on August 1, 2024, excluding the acquisition of the assets of Cook Medical.

Merit does not provide guidance for GAAP reported financial measures (other than revenue) or a reconciliation of forward-looking non-GAAP financial measures to the most directly comparable GAAP reported financial measures (other than revenue) because Merit is unable to predict with reasonable certainty the financial impact of items such as expenses related to acquisitions or other extraordinary transactions, non-cash expenses related to amortization or write-off of previously acquired tangible and intangible assets, certain severance expenses, performance-based stock compensation expenses, expenses resulting from non-ordinary course litigation or administrative proceedings and resulting settlements, governmental proceedings and changes in governmental or industry regulations. These items are uncertain, depend on various factors, and could have a material impact on GAAP reported results for the guidance period. For the same reasons, Merit is unable to address the significance of the unavailable information, which could be material to future results. Specifically, Merit is not, without unreasonable effort, able to reliably predict the impact of these items and Merit believes inclusion of a reconciliation of these forward-looking non-GAAP measures to their GAAP counterparts could be confusing to investors or cause undue reliance.

Merit's financial guidance for the year ending December 31, 2024 is subject to risks and uncertainties identified in this release and Merit's filings with the U.S. Securities and Exchange Commission (the "SEC").

Advisors

Wells Fargo acted as financial advisor to Merit and Bank of America Securities acted as financial advisor to Cook Medical. Parr Brown Gee & Loveless served as legal advisor to Merit. Ice Miller served as legal advisor to Cook Medical.

Non-GAAP Financial Measures

Although Merit's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, Merit's management believes that the non-GAAP financial measures referenced in this release may 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 referenced in this release include:

- constant currency revenue;
- non-GAAP gross profit and margin;
- non-GAAP operating income and margin;
- non-GAAP net income; and
- non-GAAP earnings per share.

Merit's management team uses these non-GAAP financial measures to evaluate Merit's profitability and efficiency, to compare operating and financial results to prior periods, to evaluate changes in the 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 measures determined in accordance with GAAP.

Readers should consider non-GAAP measures referenced 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, non-GAAP gross profit and margin, non-GAAP operating income and margin, and non-GAAP net income 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 acquisition or other extraordinary transactions, non-cash expenses related to amortization or write-off of previously acquired tangible and intangible assets, certain severance expenses, expenses resulting from non-ordinary course litigation or administrative proceedings and resulting settlements, governmental proceedings or changes in tax or industry regulations, gains or losses on disposal of certain assets, and debt issuance costs. Merit may incur similar types of expenses in the future, and the non-GAAP financial information referenced 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 referenced in this release may not be comparable with similarly titled measures of other companies. Merit urges readers to review the reconciliations of its non-GAAP financial measures 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.

Constant Currency Revenue

Merit's constant currency revenue is prepared by converting the current-period reported revenue of subsidiaries whose functional currency is a currency other than the US dollar at the applicable foreign exchange rates in effect during the comparable prior-year period and adjusting for the effects of hedging transactions on reported revenue, which are recorded in the US dollar.

Non-GAAP Gross Profit and Margin

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

Non-GAAP Operating Income and Margin

Non-GAAP operating income is calculated by adjusting GAAP operating 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 acquisitions or other extraordinary transactions, non-cash expenses related to amortization or write-off of previously acquired tangible and intangible assets, certain severance expenses, performance-based stock compensation expenses, expenses resulting from non-ordinary course litigation or administrative proceedings and resulting settlements, governmental proceedings, and changes in governmental or industry regulations. Non-GAAP operating margin is calculated by dividing non-GAAP operating income by reported net sales.

Non-GAAP Net Income

Non-GAAP net income is calculated by adjusting GAAP net income for the items set forth in the definition of non-GAAP operating income above, as well as for expenses related to debt issuance costs, gains or losses on disposal of certain assets, changes in tax regulations, and other items.

Non-GAAP EPS

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

ABOUT MERIT MEDICAL

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 more than 700 individuals. Merit employs approximately 7,000 people worldwide.

ABOUT COOK MEDICAL

Since 1963, Cook Medical has worked closely with physicians to develop technologies that eliminate the need for open surgery. Today we invent, manufacture and deliver a unique portfolio of medical devices to the healthcare systems of the world. Serving patients is a privilege, and we demand the highest standards of quality, ethics and service. We have remained family owned so that we have the freedom to focus on what we care about: patients, our employees and our communities.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this release which are not purely historical, including, without limitation, statements regarding Merit's forecasted plans, revenues, net sales, net income (GAAP and non-GAAP), operating income and margin (GAAP and non-GAAP), gross profit and margin (GAAP and non-GAAP), earnings per share (GAAP and non-GAAP), and other financial measures, future growth and profit expectations or forecasted economic conditions, or the implementation of, and results which may be achieved through, Merit's Continued Growth Initiatives program or other expense reduction initiatives, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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, 2023 (the "2023 Annual Report") and other filings with the SEC. Such risks and uncertainties include inherent risks and uncertainties associated with Merit's proposed acquisition of Cook Medical's lead management portfolio and integration of the assets and operations proposed to be acquired from Cook Medical and its ability to achieve projected

financial results, product development and other anticipated benefits of the proposed acquisition; uncertainties as to whether Merit will be successful in completing the proposed acquisition, including the risk that conditions to closing the proposed acquisition will not be satisfied; uncertainties as to whether, if the acquisition of the Cook Medical lead management portfolio is completed, Merit will achieve sales, gross and operating margin, net income and earnings per share performance consistent with its forecasts projected for the acquisition; disruptions in Merit's supply chain, manufacturing or sterilization processes; reduced availability of, and price increases associated with, commodity components and other raw materials; adverse changes in freight, shipping and transportation expenses; negative changes in economic and industry conditions in the United States or other countries, including inflation; risks relating to Merit's potential inability to successfully manage growth through acquisitions generally, including the inability to effectively integrate acquired operations or products or commercialize technology developed internally or acquired through completed, proposed or future transactions; risks associated with Merit's ongoing or prospective manufacturing transfers and facility consolidations; fluctuations in interest or foreign currency exchange rates; 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; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit; consequences associated with a Corporate Integrity Agreement executed between Merit and the U.S. Office of Inspector General – Department of Health and Human Services; difficulties, delays and expenditures relating to development, testing and regulatory approval or clearance of Merit's products, including the pursuit of approvals under the European Union Medical Device Regulation, and risks that such products may not be developed successfully or approved for commercial use; litigation and other judicial proceedings affecting Merit; 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; restrictions on Merit's liquidity or business operations resulting from its debt agreements; 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; 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 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 jurisdictions; termination 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; dependance on distributors to commercialize Merit's products in various jurisdictions outside the United States; 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; failure to introduce products in a timely fashion; price and product competition; fluctuations in and obsolescence of inventory; and other factors referenced in the 2023 Annual Report and other materials filed with the SEC.

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. Those estimates and all other forward-looking statements included in this release are made only as of the date of this release, and except as otherwise required by applicable law, Merit assumes no obligation to update or disclose revisions to estimates and all other forward-looking statements.

TRADEMARKS

Unless noted otherwise, trademarks and registered trademarks used in this release are the property of Merit Medical Systems, Inc., its subsidiaries, or its licensors. Cook Medical is a trademark of Cook Medical LLC.

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Merit Medical's WRAPSODY WAVE Trial Demonstrates Superior Patency versus Standard of Care in AV Fistula Patients

In the US pivotal trial, WRAPSODY achieved 89.8% target lesion primary patency at 6 months.

SOUTH JORDAN, Utah, September 16, 2024 (GLOBE NEWSWIRE) -- Merit Medical Systems, Inc. (NASDAQ: MMSI), a global leader of healthcare technology, today announced positive 6-month findings from the randomized arteriovenous (AV) fistula arm of its WRAPSODY Arteriovenous Access Efficacy (WAVE) pivotal trial. The data were shown at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) during a FIRST@CIRSE presentation.

WRAPSODY is a cell-impermeable endoprosthesis which is intended to extend long-term vessel patency in dialysis patients. Many patients undergoing dialysis rely on a vascular access site created in the arm called an AV fistula. The maintenance of adequate blood flow through this site is crucial for patient survival.

The AV fistula arm of the WAVE trial enrolled 245 patients at 43 sites. Patients were randomized 1:1 to WRAPSODY or percutaneous transluminal angioplasty (PTA). Target lesion primary patency in patients treated with WRAPSODY was 27 percentage points higher than patients in the PTA cohort (89.8% vs. 62.8%, $p < 0.0001$).¹ The proportion of patients who experienced an adverse event was similar between cohorts.²

“The superiority of the six-month efficacy data is compelling and provides clinicians the chance to evaluate how WRAPSODY can help us prolong the vascular access of our patients. WRAPSODY should be the new standard of care for these patients,” said Mahmood K. Razavi, MD, FSIR, FSVM, Interventional Radiologist and Medical Director of Clinical Research at St. Joseph Heart and Vascular Center in Orange, Calif., and Co-Principal Investigator of the WAVE trial. “Meeting with colleagues at CIRSE to discuss the AV fistula arm of the WAVE study was the first of what we hope to be many productive discussions,” said Robert G. Jones, FRCR, Consultant Interventional Radiologist at Queen Elizabeth Hospital Birmingham in Birmingham, England, and Co-Principal Investigator of the WAVE study. “The potential for WRAPSODY to help us safely extend vascular access for our patients is a vital component of care.”

¹ The primary efficacy endpoint was defined as the freedom from clinically driven target lesion revascularization or target lesion thrombosis through 6 months.

² The primary safety endpoint was the proportion of patients who experienced an adverse event in the 30 days following treatment that negatively affected the access or venous outflow circuit and resulted in reintervention, hospitalization, or death (not including stenosis or thrombosis).

“The data release of positive findings from the randomized AV fistula arm of the WAVE study marks a major milestone for Merit,” said Fred P. Lampropoulos, Merit’s Chairman and Chief Executive Officer. “This is an important next step in our continued efforts to seek ways to improve care for patients requiring hemodialysis treatment.”

The Merit WRAPSODY Cell-Impermeable Endoprosthesis is not approved or available for commercial distribution in the United States and may not be approved or available for sale or use in other countries. In the United States, the device is being used under an Investigational Device Exemption (IDE) from the US Food and Drug Administration (FDA). Findings from the WAVE study expand on results from the first-in-human study (WRAPSODY FIRST) and support the Premarket Approval (PMA) application to the FDA for commercial use in the United States. The device is available in Brazil and in the European Union. For additional information on Merit Medical’s WAVE study, please visit: <https://clinicaltrials.gov/ct2/show/NCT04540302>.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this release which are not purely historical, including, without limitation, statements regarding results, outcomes and applications of clinical trials, studies and investigations involving Merit’s products, safety, efficacy and patient and physician adoption of Merit’s products, Merit’s ability to procure and maintain required regulatory approvals for its products, forecasted plans, revenues and other operating and financial measures, or future growth and profit expectations or forecasted economic conditions, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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, 2023 (the “2023 Annual Report”) and other filings with the SEC. Such risks and uncertainties include inherent risks and uncertainties related to the safety, efficacy and patient and physician adoption of Merit’s products, the ability to fully enroll and the final results and outcomes of clinical trials and studies involving the Merit’s products, the ability to obtain and maintain reimbursement codes for Merit’s products, Merit’s ability to procure and maintain required regulatory approvals for its products, disruptions in Merit’s supply chain, manufacturing or sterilization processes; reduced availability of, and price increases associated with, commodity components and other raw materials; adverse changes in freight, shipping and transportation expenses; negative changes in economic and industry conditions in the United States or other countries, including inflation; risks relating to Merit’s potential inability to successfully manage growth through acquisitions generally, including the inability to effectively integrate acquired operations or products or commercialize technology developed internally or acquired through completed, proposed or future transactions; risks associated with Merit’s ongoing or prospective manufacturing transfers and facility consolidations; fluctuations in interest or foreign currency exchange rates; 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; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit; consequences associated with a Corporate Integrity Agreement executed between Merit and the U.S. Office of Inspector General – Department of Health and Human Services; difficulties, delays and expenditures relating to development, testing and regulatory approval or clearance of Merit’s products, including the pursuit of approvals under the European Union Medical Device Regulation, and risks that such products may not be developed successfully or approved for commercial use; litigation and other judicial proceedings affecting Merit; 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; restrictions on Merit’s liquidity or business operations resulting from its debt agreements; 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; 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 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 jurisdictions; termination 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; dependance on distributors to commercialize Merit’s products in various jurisdictions outside the United

States; 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; failure to introduce products in a timely fashion; price and product competition; fluctuations in and obsolescence of inventory; and other factors referenced in the 2023 Annual Report and other materials filed with the SEC.

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. Those estimates and all other forward-looking statements included in this release are made only as of the date of this release, and except as otherwise required by applicable law, Merit assumes no obligation to update or disclose revisions to estimates and all other forward-looking statements.

ABOUT MERIT MEDICAL

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 more than 700 individuals. Merit employs approximately 7,000 people worldwide.

TRADEMARKS

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