MERIT MEDICAL SYSTEMS INC
Form 8-K
July 24, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): **July 24, 2018**

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)	(IRS Employer Identification No.)

1600 West Merit Parkway 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, former address, and formal fiscal year, 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information included in this Current Report contains forward-looking statements about Merit Medical Systems, Inc., a Utah corporation (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 Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements included in this Current Report, other than statements of historical fact are forward-looking statements for purposes of these provisions, including projections of earnings, revenues or other financial items, statements of the plans and objectives of our management for future operations or transactions, statements concerning proposed new products or services, statements regarding the integration, development or commercialization of any business or assets acquired from other parties, statements regarding future economic conditions or performance, and statements of assumptions underlying any of the foregoing. These 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 the forward-looking statements. Such risks, uncertainties and factors include those described in our Annual Report on Form 10-K for the year ended December 31, 2017 (filed with the SEC on March 1, 2018), our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 (filed with the SEC on May 10, 2018), and our other filings with the SEC. 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, p 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 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 it will make additional updates or corrections. Although Merit believes that the assumptions and expectations reflected in the forward-looking statements included or incorporated by reference in this prospectus are reasonable, its actual results will likely differ, and may differ materially, from anticipated results. Readers should not unduly rely on any such forward-looking statements.

Item 7.01 Regulation FD Disclosure.

On July 24, 2018, Merit announced the commencement of an offering of 3,500,000 shares of its common stock, which amount does not include additional shares that may be offered pursuant to an over-allotment option granted to the participating underwriters in connection therewith (the Offering). A copy of the press release announcing the commencement of the Offering is attached as Exhibit 99.1 to this Current Report.

In connection with the Offering, Merit has provided prospective investors with a prospectus supplement (this prospectus supplement) containing the following disclosure summarizing its business and results of operations and noting certain recent developments:

Our Business

We are a leading manufacturer and marketer of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. We strive to be the most customer-focused company in

healthcare. We are determined to make a difference by understanding our customers needs and innovating and delivering a diverse range of products that improve the lives of people and communities throughout the world. We believe that long-term value is created for our customers, employees, shareholders, and communities when we focus outward and are determined to deliver an exceptional customer experience.

We design, develop, market, and manufacture, through our own operations and contract manufacturers, approximately 190 innovative medical products that offer a high level of quality, value and safety to our customers, as well as the patients they serve. We have a direct sales force presence in 21 countries.

Our products are used in the following clinical areas:

- diagnostic and interventional cardiology
- neurointerventional radiology
- electrophysiology
- interventional pulmonology
- orthopaedic spine surgery
- endoscopy
- pain management
- intensive care
- ultrasound
- interventional radiology
- vascular, general, and thoracic surgery
- cardiac rhythm management
- interventional nephrology
- interventional oncology
- outpatient access centers
- computed tomography
- interventional gastroenterology

We currently conduct our business through two financial reporting segments: cardiovascular (which includes four of our five core product groups, namely, peripheral intervention, cardiac intervention, interventional oncology and spine, and cardiovascular and critical care) and endoscopy. Our five core product groups are as follows:

- **Peripheral intervention**, which includes products designed to alleviate patient suffering from peripheral vascular and nonvascular diseases;

- **Cardiac intervention**, which includes products designed to aid in the treatment of various cardiac conditions specific to interventional cardiology and electrophysiology, including cardiac rhythm management and cardiac resynchronization therapy;

- **Interventional oncology and spine**, which includes vertebral augmentation products for the treatment of vertebral compression fractures as well as medical devices used to treat metastatic spine tumors;

- **Cardiovascular and critical care**, which includes products designed for infection prevention, clinician safety and hemodynamic monitoring, and custom procedure packs; and

- **Endoscopy**, which integrates advanced non-vascular stent technology with balloon dilators, inflation devices, guide wires, procedure kits, and other devices used by gastroenterologists, endoscopists, pulmonologists, and thoracic and general surgeons.

We provide our products to hospitals and clinic-based cardiologists, radiologists, neurologists, nephrologists, vascular surgeons, orthopaedic surgeons, interventional gastroenterologists and pulmonologists, endoscopists, thoracic surgeons, physiatrists (pain management physicians), general surgeons, thoracic surgeons, oncologists, electrophysiologists, technicians, and nurses. Hospitals and acute care facilities in the United States generally purchase our products through our direct sales force, distributors, OEM partners, or custom procedure tray manufacturers who assemble and combine our products in custom kits and packs. Outside the United States, hospitals and acute care facilities generally purchase our products through our direct sales force, or, in the absence of a sales force, through independent distributors or OEM partners.

Our business strategy focuses on four target areas as follows:

- enhancing growth and profitability through research and development, sales model optimization, strategic acquisitions and alliances, cost discipline, and operational focus;

- optimizing our operational capability through lean processes, cost effective environments and asset utilization;

- targeting high-growth, high-return opportunities by understanding, innovating, and delivering in our core product groups; and

- maintaining a highly disciplined, customer-focused enterprise guided by strong core values to globally address unmet or underserved healthcare needs.

We believe that successful introduction and adoption of new products should help us continue to strengthen our product portfolio, achieve greater market penetration, and, if successful, drive top-line growth. We believe the following products, which we introduced to our product portfolio in the United States or Europe since the third quarter of 2016 or are developing, will help us pursue our growth objectives in 2018:

- Achieve® Automatic Biopsy System(1)
- Tru-Cut® Biopsy Device(1)
- Aspira® Pleural Effusion Drainage System(1)
- SwiftNINJA® Steerable Microcatheter
- TWISTER® PLUS Rotatable Retrieval Device
- PreludeSYNC Radial Compression Device
- HeRO® Graft
- True Form Guide Wire
- InQwire® Amplatz Guide Wire
- Critical care products acquired from Argon Medical Devices, Inc. in January 2017
- FLO40XR Hemostasis Valve
- Prelude IDeal Hydrophilic Sheath Introducer
- PreludeSYNC Distal Access Device
- DiamondTOUCH Digital Inflation Device
- Enhanced CorVocet Biopsy Device
- ReSolve CirQ Nephrostomy Catheter
- Temno® Soft Tissue Biopsy System(1)
- Aspira® Peritoneal Drainage System(1)
- CorVocet Biopsy System
- Elation® GI & Pulmonary Balloons
- EmboCube Embolization Gelatin
- Prelude Choice Hemostasis Valve Adapter
- Super HeRO® Adapter
- Heartspan® Transseptal Sheath
- QuadraSphere® Q2 Microsphere
- DualCap® disinfection and protection products
- Prelude Pursuit Splittable Sheath Introducer
- Prelude Choice Hemostasis Valve Adapter
- Merit Pursue Microcatheter
- basixTAU Inflation Device
- Bone & Spine Biopsy Device
- FastBreak Breakaway Connector

- NvisionVLE® Imaging System(2)

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(1) Acquired from Becton, Dickinson and Company in February 2018. For additional information, see note 17 (Subsequent Events) to our audited consolidated financial statements included in our 2017 Annual Report, which is incorporated by reference herein.

(2) Distributed pursuant to an exclusive worldwide distributor agreement with NinePoint Medical, Inc., executed in April 2018. For additional information, see note 16 (Subsequent Events) in the interim consolidated financial statements included in our Q1 2018 Quarterly Report, which is incorporated by reference herein.

The success of our products is enhanced by the extensive experience of our management team in the healthcare industry, our experienced direct sales force and distributors, our ability to provide

custom procedural solutions such as kits, trays and procedural packs at the request of our customers, and our dedication to offering facility-unique solutions in the markets we serve worldwide.

Sales of our products in the United States accounted for approximately 54% and 58% of our net sales in the three months ended March 31, 2018 and the year ended December 31, 2017, respectively. In the United States, we have a dedicated, direct sales organization who are primarily focused on selling to end-user physicians, hospitals and clinics, major buying groups and integrated healthcare networks. Internationally, we employ sales representatives and contract with independent dealer organizations and custom procedure tray manufacturers to distribute our products worldwide, including territories in Europe, Africa, the Middle East, Asia, South and Central America, Oceania, and Canada. In the three months ended March 31, 2018 and the year ended December 31, 2017, our international sales accounted for approximately 46% and 42%, respectively, of our net sales.

During the three months ended March 31, 2018 and the year ended December 31, 2017, net sales generated by our top ten selling products accounted for approximately 36% and 37%, respectively, of our total net sales. Sales of our inflation devices (including our Big60® device sold within our endoscopy segment and kits and packs which include inflation devices, but also include other products) accounted for approximately 11.4%, 11.4%, 12.7%, and 14.0% of our net sales for the three months ended March 31, 2018 and the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we employed 4,876 people. As of June 30, 2018, we employed approximately 5,400 people.

For a discussion of our results of operations and other financial information for the three months ended March 31, 2018 and 2017 and the years ended December 31, 2017, 2016 and 2015, including a discussion of trends that we expect to impact our business in the remainder of 2018, please review the sections entitled Management s Discussion and Analysis of Financial Condition and Results of Operations in each of our Q1 2018 Quarterly Report and our 2017 Annual Report, each of which is incorporated by reference herein.

Recent Developments

Certain Preliminary Financial Results

On July 23, 2018, we announced preliminary financial results for the quarter ended June 30, 2018, including:

- net sales for the three months ended June 30, 2018 of $224.8 million, compared to $186.5 million in net sales for the three months ended June 30, 2017;

- earnings per share for the three months ended June 30, 2018 of $0.21, compared to earnings per share of $0.19 for the three months ended June 30, 2017;

- gross margin for the three months ended June 30, 2018 of 44.5%, compared to gross margin of 43.4% and

45.1% for the three months ended March 31, 2018 and June 30, 2017, respectively;

- non-GAAP earnings per share* for the three months ended June 30, 2018 of $0.43, compared to non-GAAP earnings per share* of $0.36 for the three months ended June 30, 2017; and

- non-GAAP gross margin* for the three months ended June 30, 2018 of 48.9%, compared to non-GAAP gross margin* of 47.5% and 48.3% for the three months ended March 31, 2018 and June 30, 2017, respectively.

The increase in net sales in the second quarter of 2018 was driven primarily by demand for our legacy products, revenue earned from a full fiscal quarter selling products acquired from Becton, Dickinson and Company, or BD, (in February 2018), and continued growth in international markets. Second quarter 2018 GAAP and non-GAAP gross margin were positively impacted by manufacturing efficiencies, improved obsolescence, and sales from our biopsy and drainage products (acquired from BD), partially offset by an increase in sales of certain of our legacy products (which traditionally have had a lower margin than certain of our newer products) and other changes in our product mix. In addition to the factors outlined in our 2017 Annual Report and Q1 2018 Quarterly Report, in the remainder of 2018, we expect that our net sales will be positively impacted by recently-awarded tenders, anticipated releases of new products, commencement of production of the Laurane Medical product line in our Irish facility, our acquisition of product distribution agreements for the DirectACCESS Medical FirstChoice Ultra High Pressure PTA Balloon Catheter, and the execution of a product distribution agreement for the QXMédical Q50® PLUS Stent Graft Balloon Catheter. Additionally, a competitor has recently experienced substantial global supply shortages due to internal issues, which has resulted in increased demand for our Merit Laureate® Hydrophilic Guide Wires, our offering of microcatheters (including the Merit Maestro®, SwiftNINJA® and the recently introduced Merit Pursue Microcatheter), our Impress® Diagnostic Catheters and our vascular sheaths (including the recently introduced Prelude IDeal and PreludeEASE product offerings). Moreover, we expect that our net income for the remainder of 2018 will be positively impacted by continued manufacturing efficiencies, cost-saving measures, and sales of our biopsy and drainage products, partially offset by several demand-based factors, including changes in our product mix, increases in revenue in certain markets served by distributors, and increases in labor costs and logistical expenses of addressing global supply requirements.

The amounts set forth above are preliminary estimates of certain financial results for the three months ended June 30, 2018. These preliminary results are based on currently available information as of the date of this prospectus supplement and do not present all necessary information for an understanding of our results of operations for the three months ended June 30, 2018. This financial information has been prepared by and is the responsibility of our management. Our independent registered public accounting firm, Deloitte & Touche LLP, has not audited, reviewed or completed any procedures with respect to this preliminary financial data or the accounting treatment thereof and does not express an opinion or any other form of assurance with respect thereto. We expect to complete our unaudited financial statements for the quarter ended June 30, 2018 subsequent to the completion of this offering. It is possible that we or Deloitte & Touche LLP may identify items that require us to make adjustments to the financial information set forth above and those changes could be significant.

For additional preliminary results, see Summary Consolidated Financial Information Preliminary Financial Results for Second Quarter 2018. Additionally, please see the sections in this prospectus supplement entitled Non-GAAP Financial Measures and Summary Consolidated Financial Information Non-GAAP Financial Measures for further information regarding the non-GAAP measures presented above (each of which is identified with an asterisk), as well as tables reconciling such measures to their corresponding GAAP measures.

2018 Incentive Plan

At our annual meeting of shareholders held on May 24, 2018, our shareholders voted to approve our 2018 Long-Term Incentive Plan, or the 2018 Incentive Plan, which allows us to issue up to 3.1 million shares of common stock for future equity grants to directors, officers, employees and other eligible participants.

The 2018 Incentive Plan superseded our 2006 Long-Term Incentive Plan, or the 2006 Incentive Plan, and is the compensation plan under which we intend to grant stock options, restricted stock and other equity-based awards to eligible participants going forward. Although no further awards will be made under our 2006 Incentive Plan, awards previously issued under the 2006 Incentive Plan will remain in effect.

For more information, see our 2018 Proxy Statement.

In connection with the Offering, Merit provided prospective investors with the following amended and updated risk factors.

We may be unable to successfully manage growth, particularly if accomplished through acquisitions, and the integration of acquired businesses may present significant challenges that could harm our operations.

Successful implementation of our business strategy will require that we effectively manage any associated growth. To manage growth effectively, our management will need to continue to implement changes in certain aspects of our business, to improve our information systems, infrastructure and operations to respond to increased demand, to attract and retain qualified personnel, and to develop, train, and manage an increasing number of management-level and other employees. Growth could place an increasing strain on our management, sales and other personnel, and on our financial, product design, marketing, distribution and other resources, and we could experience operating difficulties. Any failure to manage growth effectively could have a material adverse effect on our business, operations or financial condition.

Over the past several years, we have completed a series of significant acquisitions and, at any given time, we may be considering a number of potential further acquisitions and strategic transactions, certain of which may also be significant. As we grow through acquisitions, we face the additional challenges of integrating the operations, culture, information management systems and other characteristics of the acquired entity with our own. Efforts to integrate future acquisitions may be hampered by delays, the loss of certain employees, suppliers or customers, proceedings resulting from employment terminations, culture clashes, unbudgeted costs, and other issues, which may occur at levels that are more severe or prolonged than anticipated. Additionally, past and future acquisitions may increase the risks of competition we face (as further discussed under We may be unable to compete in our markets, particularly if there is a significant change in relevant practices or technology below) by, among other things, extending our operations into industry segments and product lines where we have few existing customers or qualified sales personnel and limited expertise. For example, although we acquired certain tunneled home drainage catheter and soft tissue core needle biopsy products from BD in February 2018, BD retained other products that directly compete with the products we acquired. As BD is a larger company with a more well-established market presence in such product lines, we may be unable to realize expected benefits from the acquisition in the timeframe anticipated or at all.

We have incurred, and will likely continue to incur, significant expenses in connection with negotiating and consummating various acquisition and other strategic transactions, and we may inherit significant liabilities in connection with prospective acquisitions or other strategic transactions, including regulatory, infringement, product liability, discrimination or other legal claims or issues. In addition, we may not realize competitive advantages, synergies or other benefits anticipated in connection with any such acquisition or other transaction. If we do not adequately identify targets for, or manage issues related to, our future acquisitions and similar transactions, such transactions may have an adverse effect on our business, operations or financial condition.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing clearances and approvals from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific uses. We are prohibited from marketing or promoting any uncleared or unapproved use of our product. However, physicians may use these products in ways or circumstances other than those strictly within the scope of the regulatory approval or clearance. The use of our products for unauthorized purposes could arise from our sales personnel or distributors violating our policies by providing information or recommendations about such unauthorized uses. Consequently, claims may be asserted by the FDA or other enforcement agencies that we are

not in compliance with applicable laws or regulations or have

improperly promoted our products for uncleared or unapproved uses. The FDA or such other agencies could require a recall of products or allege that our promotional activities misbrand or adulterate our products or violate other legal requirements, which could result in investigations, prosecutions, fines or other civil or criminal actions.

The FDA regulatory clearance process is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products.

Before we can introduce a new device or a new use of or a claim for a cleared device in the United States, we must generally obtain clearance from the FDA through the 510(k) premarket notification process or approval through a PMA application, unless an exemption from premarket review or an alternative procedure, such as a *de novo* risk based classification or a humanitarian device exemption, applies. The FDA clearance and approval processes for medical devices are expensive, uncertain and time-consuming.

If human clinical trials of a medical device are required for FDA clearance or approval and the device presents a significant risk, the sponsor of the trial must file an IDE application with the FDA prior to commencing such trials in the U.S. Submission of an IDE application does not ensure that the IDE will become effective. If the IDE application is approved, there can be no assurance that the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. For clinical trials involving a device that does not present a significant risk, the sponsor is not required to obtain FDA approval of an IDE, but the sponsor must obtain the review and approval of an institutional review board. Both significant risk and non-significant risk trials are subject to additional FDA regulations, including a requirement to obtain informed consent, reporting and recordkeeping requirements, and other requirements. We, the FDA, or the institutional review board, may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Changes to 510(k) cleared or PMA approved devices, including manufacturing changes, product enhancements and product line extensions, may require a new 510(k) clearance or approval of a PMA supplement. For devices marketed under an approved PMA, we must submit a PMA supplement to the FDA for review and approval prior to making a change to the device that affects the safety or effectiveness of the device, including changes to the design, manufacturing or labeling of the device. Likewise, for 510(k)-cleared devices, we must obtain new FDA 510(k) clearance when there is a major change or modification in the intended use, or a change or modification of the device that could significantly affect the safety or effectiveness of the device. In some cases, clinical data may be required to support a PMA supplement or 510(k) premarket notification for a device modification.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission or a PMA supplement in the first instance, but the FDA may review the manufacturer s decisions not to seek a new 510(k) or PMA supplement. We may make changes to our cleared products without seeking additional clearances or approvals if we determine such clearances or approvals are not necessary and document the basis for that conclusion. However, the FDA may disagree with our determination or may require additional information, including clinical data, to be submitted before a determination is made, in which case we may be required to delay the introduction and marketing of our modified products, redesign our products, conduct clinical trials to support any modifications and pay significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization.

There is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for any product on a timely basis or at all. Further, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Delays in receipt of,

or failure to obtain, regulatory clearances for any product enhancements or new products we develop would result in delayed or no realization of revenue from such product enhancements or new products and in substantial additional costs, which could decrease our profitability.

In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. We cannot assure you that we will successfully maintain the clearances or approvals we have received or may receive in the future. The loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could also have a material adverse effect on our business.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA or other governmental authorities, and if we fail to do so, we may be subject to sanctions that may materially harm our business.

Our products are subject to medical device reporting regulations, which require us to report to the FDA any information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or contribute to a death or serious injury. Our obligation to report under the medical device reporting regulations is triggered on the date on which we become aware of information that reasonably suggests a reportable adverse event occurred. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or if the product characteristic that caused the adverse event is removed in time from our products. If we fail to comply with our medical device reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, demand or initiate a product recall, seize our products, or delay the clearance of our future products.

We generally offer a limited warranty for the return of product due to defects in quality and workmanship. We attempt to estimate our potential liability for future product returns and establish reserves on our financial statements in amounts that we believe will be sufficient to address our warranty obligations; however, our actual liability for product returns may significantly exceed the amount of our reserves. If we underestimate our potential liability for future product returns, or if unanticipated events result in returns that exceed our historical experience, our financial condition and operating results could be materially harmed.

We may be unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate supply, we must forecast our inventory needs and place orders with our suppliers based on estimates of future demand for particular products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy and customer acceptance of new products, product introductions by our competitors, an increase or decrease in customer demand for our products or for products of our competitors, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would impact our gross margin. Conversely, if we underestimate customer demand for our products, our manufacturing facilities may not be able to deliver products to meet our order requirements, which could damage our reputation and customer relationships.

Our forecasts of customer demand and related decisions that we make about production levels may take into account potential opportunities created by regulatory issues, supply disruptions or other challenges experienced by our competitors. We generally do not know the extent and

cannot predict the duration of these challenges experienced by our competitors. As a result, our estimates

about related increased demand for our products are inherently uncertain and subject to change. If our estimates incorrectly forecast the extent or duration of this increased demand, or the product types to which it relates, our revenues, margins and earnings could be adversely affected.

Finally, in connection with the Offering, Merit provided prospective investors with the following non-GAAP information.

Non-GAAP Financial Measures

Although our financial statements are prepared in accordance with accounting principles which are generally accepted in the United States of America, or GAAP, this prospectus supplement includes non-GAAP financial measures which are derived on the basis of methodologies other than in accordance with GAAP. Such measures include:

- constant currency revenue;
- core revenue;
- core revenue on a constant currency basis;
- non-GAAP net income;
- non-GAAP earnings per share; and
- non-GAAP gross margin.

Our management team believes that the non-GAAP financial measures referred to in this prospectus supplement provide investors with useful information regarding the underlying business trends and performance of our ongoing operations and can be useful for period-over-period comparisons of such operations. Additionally, our management team uses these non-GAAP financial measures to evaluate our profitability and efficiency, to compare operating results to prior periods, to evaluate changes in the operating results of each of our operating segments, and to measure and allocate financial resources internally. However, our management does not consider such non-GAAP measures in isolation or as an alternative to such measures determined in accordance with GAAP.

You should consider any non-GAAP measures referred to in this prospectus supplement in addition to, and not as a substitute for, financial reporting measures prepared in accordance with GAAP. Such non-GAAP financial measures exclude some, but not all, items that may affect our net sales, net income, earnings per share, and gross margin. In addition, they are subject to inherent limitations as they reflect the exercise of judgment by management about which items are excluded. We believe it is useful to exclude such items in the calculation of constant currency revenue, core revenue, core revenue on a constant currency basis, non-GAAP net income, non-GAAP earnings per share, and non-GAAP gross margin (in each case, as illustrated under the caption Summary Consolidated Financial Information) because such amounts in any specific period may not directly correlate to the underlying performance of our business operations and can vary significantly between periods as a result of factors such as new acquisitions, non-cash expense related to amortization of previously acquired tangible and intangible assets and in-process research, unusual compensation expenses, and expenses resulting from non-ordinary course litigation or governmental proceedings. We may incur similar types of expenses in the future, and the non-GAAP financial information included in this prospectus supplement 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 prospectus supplement may not be comparable with similarly titled measures of other companies.

We urge investors and potential investors to review the reconciliations of our non-GAAP financial measures to the comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business or results of operations.

Non-GAAP financial measures used in this prospectus supplement are defined as follows:

- *Constant Currency Revenue*. Our net sales on a constant currency basis is calculated by translating the current-period reported revenue of subsidiaries whose functional currency is other than the U.S. dollar at the applicable foreign exchange rates in effect during the comparable prior-year period.

- *Core Revenue and Core Revenue on a Constant Currency Basis*. Our core revenue for a period is calculated by excluding net sales attributable to certain acquisitions and strategic transactions from reported net sales for such period. We compare core revenue in the current period against a baseline (i.e., GAAP revenue) in the prior period. Core revenue on a constant currency basis is defined as current-period core revenue plus the foreign exchange impact related to those core sales, using the applicable foreign exchange rates in effect for the comparable prior-year periods presented.

- *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 previously acquired tangible and intangible assets, unusual compensation expenses, unusual expenses resulting from non-ordinary course litigation, governmental proceedings or changes in tax regulations, as well as other items set forth in the table below.

- *Non-GAAP Earnings Per Share*. Non-GAAP earnings per share is calculated 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, inventory mark-up related to acquisitions and severance.

In the tables below, we have included certain unaudited, non-GAAP financial measures, with reconciliations to the most directly comparable GAAP financial measures during the periods shown in the footnotes below. You should consider any non-GAAP financial measures referred to in this prospectus supplement in addition to, and not as a substitute for, financial reporting measures prepared in accordance with GAAP. For additional information, see Non-GAAP Financial Measures.

	Three months ended June 30,	
	2018	**2017**
	(unaudited; in thousands, except gross margin and per share data)	
Non-GAAP Financial Measures:		
Core revenue(3)	$ 208,446	$ 186,549
Non-GAAP net income(4)	22,370	18,285
Non-GAAP earnings per share(4)	0.43	0.36
Non-GAAP gross margin(5)	48.9%	48.3%

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	Three months ended March 31,	
	2018	2017
	(unaudited; in thousands, except gross margin and per share data)	
Non-GAAP Financial Measures:		
Non-GAAP net income(4)	$ 15,927	$ 12,671
Non-GAAP earnings per share(4)	0.31	0.28
Non-GAAP gross margin(5)	47.5%	48.3%

Notes to Financial Tables:

(1) Constant currency revenue, or net sales on a constant currency basis, is a non-GAAP financial measure prepared by translating the current-period reported net sales of subsidiaries whose functional currency is other than the U.S. dollar at the applicable foreign exchange rates in effect during the comparable prior period.

Our constant currency revenue during the three months ended June 30, 2018 was $221.2 million (an adjustment of $(3.6) million from reported net sales, calculated using applicable 2017 foreign exchange rates).

(2) Gross margin refers to our gross profit as a percentage of net sales.

(3) We calculate core revenue for the current period against a prior period GAAP revenue baseline. As such, core revenue is (a) GAAP revenue less revenue attributable to certain acquisitions and strategic transactions (in the case of the current fiscal year period being presented) and (b) GAAP revenue (in the case of prior fiscal year periods). For the three months ended June 30, 2018, our excluded acquisitions and strategic transactions included (i) Osseon LLC in July 2017, (ii) Laurane Medical S.A.S. in August 2017, (iii) ITL Healthcare Pty. Ltd. in October 2017, (iv) assets acquired in from Becton, Dickinson and Company in February 2018, and (v) the distribution agreement with NinePoint Medical, Inc. in April 2018.

The following table shows our core revenue and core revenue on a constant currency basis for the three-month periods ended June 30, 2018 and 2017 and reconciles such amounts to GAAP net sales during the periods:

	Three months ended June 30,	
	2018	2017
	(in thousands; non-GAAP data unaudited)	
GAAP net sales	$ 224,810	$ 186,549
Net sales from excluded acquisitions	(16,364)	
Core revenue	**$ 208,446**	**$ 186,549**
Impact of foreign exchange on core revenue	(3,645)	
Core revenue on a constant currency basis	**$ 204,801**	**$ 186,549**

The constant currency core revenue adjustment of $(3.6) million for the three months ended June 30, 2018 was calculated using the applicable average foreign exchange rates for the three months ended June 30, 2017.

(4) Non-GAAP net income and non-GAAP earnings per share include net income adjusting for amortization of intangibles, inventory mark-up and severance expenses related to acquisitions, acquisition-related costs, and other adjustments as illustrated further below.

The following tables set forth our non-GAAP net income and non-GAAP earnings per share for the three-month periods ended June 30, 2018 and 2017 and the three-month periods ended March 31, 2018 and 2017, and reconcile such information to our GAAP net income and earnings per share during the same periods.

	Three months ended June 30, 2018			
	Pre-Tax	Tax Impact(a)	After-Tax	Per Share Impact
	(in thousands, except per share data; non-GAAP data unaudited)			
GAAP Net Income	**$ 11,565**	**$ (624)**	**$ 10,941**	**$ 0.21**
Non-GAAP Adjustments:(b)				
Cost of sales				
Amortization of intangibles	7,937	(2,061)	5,876	0.12
Inventory mark-up related to acquisitions	1,888	(485)	1,403	0.03
Operating expenses				
Severance	163	(38)	125	0.00
Acquisition-related(c)	620	(159)	461	0.01
Fair value adjustment to contingent consideration(d)	178	(46)	132	0.00
Long-term asset impairment charge(e)	29	(7)	22	0.00
Acquired in-process research and development	306	(79)	227	0.00
Amortization of intangibles	2,466	(655)	1,811	0.03
Special legal expense(f)	1,646	(423)	1,223	0.02
Other (income) expense				
Amortization of long-term debt issuance costs	201	(52)	149	0.00
Non-GAAP Net Income	**$ 26,999**	$ (4,629)	**$ 22,370**	**$ 0.43**
Diluted Shares				**52,154**

	Three months ended June 30, 2017			
	Pre-Tax	Tax Impact(a)	After-Tax	Per Share Impact
	(in thousands, except per share data; non-GAAP data unaudited)			
GAAP Net Income	**$ 11,313**	**$ (1,830)**	**$ 9,483**	**$ 0.19**
Non-GAAP Adjustments:(b)				
Cost of sales				
Amortization of intangibles	4,917	(1,840)	3,077	0.06
Inventory mark-up related to acquisitions	985	(383)	602	0.01
Operating expenses				
Severance	128	(50)	78	0.00
Acquisition-related(c)	1,736	(552)	1,184	0.02
Fair value adjustment to contingent consideration(d)	(18)	7	(11)	0.00
Long-term asset impairment charge(e)	2	(1)	1	0.00
Acquired in-process research & development	75	(29)	46	0.00
Amortization of intangibles	1,329	(512)	817	0.02
Special legal expense(f)	3,657	(1,422)	2,235	0.04
Other (income) expense				
Gain from bargain purchase(g)	669		669	0.01
Amortization of long-term debt issuance costs	171	(67)	104	0.00
Non-GAAP Net Income	**$ 24,964**	**$ (6,679)**	**$ 18,285**	**$ 0.36**
Diluted Shares				51,188

	Three months ended March 31, 2018			
	Pre-Tax	Tax Impact(a)	After-Tax	Per Share Impact
	(in thousands, except per share data; non-GAAP data unaudited)			
GAAP Net Income	**$ 6,359**	**$ (1,090)**	**$ 5,269**	**$ 0.10**
Non-GAAP Adjustments:(b)				
Cost of sales				
Amortization of intangibles	6,463	(1,606)	4,857	0.10
Inventory mark-up related to acquisitions	1,873	(481)	1,392	0.03
Operating expenses				
Acquisition-related(c)	1,970	(506)	1,464	0.03
Fair value adjustment to contingent consideration(d)	40	(10)	30	0.00
Long-term asset impairment charge(e)	56	(14)	42	0.00
Amortization of intangibles	2,000	(532)	1,468	0.03
Special legal expense(f)	1,691	(435)	1,256	0.02
Other (income) expense				
Amortization of long-term debt issuance costs	201	(52)	149	0.00
Non-GAAP Net Income	**$ 20,653**	**$ (4,726)**	**$ 15,927**	**$ 0.31**
Diluted Shares				51,910

	Three months ended March 31, 2017			
	Pre-Tax	Tax Impact(a)	After-Tax	Per Share Impact
	(in thousands, except per share data; non-GAAP data unaudited)			
GAAP Net Income	**$ 15,493**	**$ (690)**	**$ 14,803**	**$ 0.32**
Non-GAAP Adjustments:(b)				
Cost of sales				
Amortization of intangibles	4,826	(1,805)	3,021	0.07
Inventory mark-up related to acquisitions	1,893	(736)	1,157	0.03
Operating expenses				
Severance	1,216	(473)	743	0.02
Acquisition-related(c)	1,552	(282)	1,270	0.03
Fair value adjustment to contingent consideration(d)	37	(15)	22	0.00
Long-term asset impairment charge(e)	18	(7)	11	0.00
Amortization of intangibles	1,343	(518)	825	0.02
Special legal expense(f)	4,840	(1,883)	2,957	0.06
Other (income) expense				
Gain on bargain purchase(g)	(12,243)		(12,243)	(0.27)
Amortization of long-term debt issuance costs	172	(67)	105	0.00
Non-GAAP Net Income	**$ 19,147**	**$ (6,476)**	**$ 12,671**	**$ 0.28**
Diluted Shares				45,820

Notes to reconciliation tables for non-GAAP net income and non-GAAP earnings per share.

(a) Reflects the tax effect of each non-GAAP adjustment.

(b) The non-GAAP adjustments referenced do not reflect stock-based compensation expense of (i) approximately $1.6 million and $1.1 million for the three months ended June 30, 2018 and 2017, and (ii) approximately $1.3 million and $0.6 million for the three-month periods ended March 31, 2018 and 2017, respectively.

(c) Represents selling, general and administrative expenses related to acquisitions during the period.

(d) Represents changes in the fair value of contingent consideration liabilities and contingent receivables as a result of acquisitions.

(e) Represents abandoned patents.

(f) Represents legal expenses incurred in responding to an inquiry from the U.S. Department of Justice. See note 14 (Commitments and Contingencies) to the interim consolidated financial statements included in our Q1 2018 Quarterly Report and Item 3 (Legal Proceedings) of our 2017 Annual Report for more information. Such legal expenses incurred from October 2016 to June 30, 2018 (on a quarterly basis) are shown in the table below:

	Three months ended						
	June 30, 2018	**March 31, 2018**	**Dec. 31, 2017**	**Sept. 30, 2017**	**June 30, 2017**	**March 31, 2017**	**Dec. 31, 2016**
Special legal expense							
(*in thousands*)	$ 1,646	$ 1,691	$ 2,001	$ 2,118	$ 3,657	$ 4,840	$ 1,016

The information provided above is not an indication of the amount of expected future legal expense in connection with our response to the U.S. Department of Justice inquiry referenced above.

(g) Represents the gain on bargain purchase realized from the acquisition of the critical care division of Argon Medical Devices, Inc. in January 2017.

(5) Non-GAAP gross margin is calculated by adjusting our gross profit by amounts recorded for amortization of intangible assets and inventory mark-up related to acquisitions. The following tables show our non-GAAP gross margins for the periods noted and reconcile such measures to our GAAP gross margin for the same period.

	Three Months Ended June 30,	
	2018	**2017**
	(in thousands, except percentages; non-GAAP data unaudited)	
Net sales	$ 224,810	$ 186,549
GAAP gross profit	$ 100,009	$ 84,141
as a percentage of net sales	44.5%	45.1%
Non-GAAP adjustments (add back):		
Amortization of intangibles	7,937	4,917
Inventory mark-up related to acquisitions	1,888	985
Non-GAAP gross profit	$ 109,834	$ 90,043
as a percentage of net sales	48.9%	48.3%

	Three Months Ended March 31,	
	2018	**2017**
	(in thousands, except percentages; non-GAAP data unaudited)	
Net sales	$ 203,035	$ 171,069
GAAP gross profit	$ 88,056	$ 75,942
as a percentage of net sales	43.4%	44.4%
Non-GAAP adjustments (add back):		
Amortization of intangibles	6,463	4,826
Inventory mark-up related to acquisitions	1,873	1,893
Non-GAAP gross profit	$ 96,392	$ 82,661
as a percentage of net sales	47.5%	48.3%

The information set forth in this Item 7.01 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, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Merit Medical Systems, Inc., dated July 24, 2018, entitled Merit Medical Announces Commencement of Public Offering of Common Stock.

EXHIBIT INDEX TO CURRENT REPORT ON FORM 8-K

DATED JULY 24, 2018

EXHIBIT NUMBER	DESCRIPTION
99.1	Press release issued by Merit Medical Systems, Inc., dated July 24, 2018, entitled Merit Medical Announces Commencement of Public Offering of Common Stock.

SIGNATURES

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

MERIT MEDICAL SYSTEMS, INC.

Date: July 24, 2018

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