

MERIT MEDICAL SYSTEMS INC
Form S-3/A
December 23, 2010
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As Filed with the Securities and Exchange Commission on December 23, 2010

Registration No. 333-169012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT NO. 2 TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Utah
(State or other jurisdiction of incorporation or organization)

87-0447695
(I.R.S. Employer Identification Number)

1600 West Merit Parkway, South Jordan, Utah 84095

(801) 253-1600

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(Address, including zip code, and telephone number, including area code, of Registrant's principal executive officer)

Kent W. Stanger
Chief Financial Officer
1600 West Merit Parkway
South Jordan, Utah 84095
(801) 253-1600

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:
Brian G. Lloyd
Gregory S. Nelson
Parr Brown Gee & Loveless
185 South State Street, Suite 800
Salt Lake City, Utah 84111
(801) 532-7840

Approximate date of commencement of the proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller public company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered(1)	Amount to be Registered	Proposed maximum aggregate offering price(3)	Amount of registration Fee
Common stock, without par value(2)			
Warrants(2)			
Units(2)			
Debt Securities(2)			
Total	\$ 150,000,000	\$ 150,000,000	\$ 10,696(4)

(1) Any securities registered hereunder may be sold separately or as units with other securities registered hereunder.

(2) There is being registered hereunder such indeterminate amount of common stock, warrants, units and debt securities as may from time to time be issued by the Registrant at indeterminate prices and as may be issuable upon conversion, redemption, exchange, exercise or settlement of any securities registered hereunder, including any applicable anti-dilution provisions, or as a result of any stock splits, stock dividends or similar transactions relating to the securities registered hereunder. In no event will the aggregate initial offering price of all securities issued from time to time pursuant to this registration statement exceed \$150,000,000. The proposed maximum aggregate offering price per class of security will be determined from time to time by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder.

(3) The proposed maximum aggregate offering price has been estimated solely for the purpose of calculating the registration fee pursuant to Section 457(o) under the Securities Act of 1933, as amended (the Securities Act). Rule 457(o) permits the registration fee to be calculated on the basis of the maximum offering price of all the securities listed and therefore, pursuant to General Instruction II.D of Form S-3 under the Securities Act, the foregoing table does not specify by each class information as to the amount to be registered, the proposed maximum offering price per security or the proposed maximum aggregate offering price.

(4) The Registrant has previously paid the full amount of the registration fee.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)

Dated December 23, 2010

MERIT MEDICAL SYSTEMS, INC.

\$150,000,000

COMMON STOCK

DEBT SECURITIES

WARRANTS

UNITS

Under this prospectus we may offer, from time to time, in one or more series:

- shares of our common stock;
- senior and/or subordinated debt securities;
- warrants to purchase common stock and/or debt securities; and
- units consisting of two or more of these classes of securities.

We may sell any combination of these securities in one or more offerings, up to an aggregate offering price of \$ 150,000,000, on terms to be determined at the time of offering. Additionally, selling security holders named in an accompanying prospectus supplement who acquire these securities from us may offer the securities for resale, separately or in units, under this prospectus.

This prospectus describes the general terms that may apply to these securities. When we or the selling security holders decide to sell securities under this prospectus, we will describe in a prospectus supplement, which must accompany this prospectus, the securities we are offering and selling, as well as the specific amounts, prices and terms thereof. The prospectus supplements also may add, update or change information in this prospectus. You should read this prospectus and any applicable prospectus supplement before you make your investment decision.

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Our common stock is listed on the Nasdaq Global Select Market under the symbol MMSI. On December 22, 2010, the last reported sale price of our common stock was \$16.05 per share. As of the date of this prospectus, none of the other securities that we may offer by this prospectus are listed on any national securities exchange or automated quotation system. The mailing address and telephone number of our principal executives offices are 1600 West Merit Parkway, South Jordan, Utah 84095; (801) 253-1600.

The proceeds that we receive from any sales by us of the securities offered under this prospectus will be reduced by any registration and offering fees and expenses. We will receive no proceeds from any sale by selling security holders of the securities covered by this prospectus and any accompanying prospectus supplement, but we may, in some cases, pay certain registration and offering fees and expenses.

The securities may be offered and sold directly to you, through one or more underwriters, dealers and agents, or through underwriting syndicates managed or co-managed by one or more underwriters, on a continuous basis or a delayed basis. If we use any underwriters, dealers or agents to sell the securities, their names and information about their compensation will be set forth in a prospectus supplement.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

Investing in the securities offered by this prospectus and the accompanying prospectus supplement involves risks. See

Forward-Looking Statements beginning on page 2 and Risk Factors, also beginning on page 2, and similarly titled sections that may appear in or may be incorporated by reference into the prospectus supplement accompanying this prospectus prior to investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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The date of this prospectus is _____ ,

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the SEC) using a shelf registration, or continuous offering process. Under this shelf process, we may from time to time sell the securities described in this prospectus in one or more offerings up to a maximum aggregate offering price of \$150,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. This prospectus does not contain all of the information included in our registration statement. For a more complete understanding of our offering of securities, you should refer to our registration statement, including its exhibits. You should read both this prospectus and any prospectus supplement carefully, including the risks of investing in our securities discussed under Risk Factors, together with the additional information described under the heading Where You Can Find More Information. You should not assume that the information in this prospectus, any prospectus supplement or any documents incorporated by reference is accurate as of any date other than the date of the applicable document. You should rely only on the information incorporated by reference or provided in this prospectus and any prospectus supplement. We have not authorized anyone to provide you with different information.

Unless otherwise indicated in this prospectus or any prospectus supplement, or the context otherwise requires, all references to Merit Medical, our company, we, us, or our mean Merit Medical Systems, Inc. and its subsidiaries as a combined entity, except where it is made clear that the term only means the parent company or an identified subsidiary. Information contained on our website is not a part of our registration statement, this prospectus or any prospectus supplement.

ABOUT MERIT MEDICAL SYSTEMS

Merit Medical Systems, Inc. designs, develops, manufactures and markets single-use medical products for interventional and diagnostic procedures. Our focus is divided into four markets: cardiology, radiology, gastroenterology and pulmonology. We have been able to introduce new products and capture significant market share because of our expertise in product design, our proprietary technology and our skills in injection and insert molding. Our innovative products are designed to enable physicians and other healthcare professionals to perform interventional and diagnostic procedures with enhanced patient care and efficiency.

Our cardiology and radiology products are designed to assist in diagnosing and treating coronary artery disease and peripheral vascular disease. These innovative products aid in conducting dialysis treatment for kidney failure, performing drainage procedures and clearing clots, as well as removing foreign objects from the vasculature, providing access into vasculature and recording hemo-dynamic pressure. Our cardiology and radiology products, which are distributed through our direct sales force and third-party distributors, include inflation devices, snares, non-vascular stents, aspiration extraction catheters, angiographic catheters, dialysis catheters, micro catheters, micro access products, guide wires, needles, safety products, therapeutic infusion catheters and accessories, drainage catheters and accessories, sheath introducers, pressure infusion bags, syringes, safety scalpels, coagulation probes, kits and procedure trays.

Our gastroenterology and pulmonary products assist physicians, nurses and technicians in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. These products, which are distributed through our direct sales force and third-party distributors, include esophageal and tracheobronchial stents pre-loaded on a catheter-based delivery system, guide wires, inflation devices and sizing devices. Our esophageal stent helps occlude esophageal tracheal fistula.

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Our Original Equipment Manufacturers (OEM) division also expands the markets in which our products are distributed on a world-wide basis. We sell molded components, sub-assembled goods and bulk non-sterile goods, which are combined with other components and/or goods from other companies and then sold under a Merit or non-Merit label. Our OEM division sells products in international and domestic markets.

Merit Medical Systems, Inc. was organized in July 1987 as a Utah corporation. We also conduct our operations through a number of domestic and foreign subsidiaries. Our principal offices are located at 1600 West Merit Parkway, South Jordan, Utah, 84095, and our telephone number is (801) 253-1600. Our website is www.merit.com.

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FORWARD-LOOKING STATEMENTS

This prospectus contains, and incorporates by reference, certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, intends, believes, estimates, potential, or continue, or the negative thereof or other common terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results will differ, and could differ materially from those projected or assumed in the forward-looking statements. Future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including possible infringement of our technology or the assertion that our technology infringes the rights of other parties; product recalls and product liability claims; collections and supplier relations; termination of supplier relationships, or failure of suppliers to perform; our inability to successfully manage growth, including growth through acquisitions; delays in obtaining regulatory approvals, or the failure to maintain such approvals; concentration of our revenues among a limited number of products and procedures; development of competing products and technologies that could render our products obsolete; lack of market acceptance of our products; delayed introduction of our products; price and product competition; changes in domestic and international economic conditions; scarcity of labor or materials necessary to conduct our operations; cost increases; healthcare policy changes; fluctuations in and obsolescence of inventory; volatility of the market price of our common stock; foreign currency fluctuations; changes in key personnel; work stoppage or transportation risks; modification or limitation of governmental or private insurance reimbursement and other factors referred to in our press releases and reports filed with the SEC. All subsequent forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are described under the Risk Factors discussion following this section.

Given these risks and uncertainties, you are cautioned not to place undue reliance on any forward-looking statements set forth in this prospectus or any prospectus supplement. All forward-looking statements are made only as of the date of the document in which they are contained and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement or to publicly announce any revision of any forward-looking statement to reflect the occurrence of any future developments or events.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described in this prospectus and any accompanying prospectus supplement, in addition to the other information contained or incorporated by reference in this prospectus and the accompanying prospectus supplement, before making an investment decision. The risks and uncertainties described below are not the only ones that we face. Additional risks and uncertainties may also impair our business operations. Any of these risks could materially and adversely affect our business, financial condition or results of operation. In such case, you may lose all or part of your investment. Some factors in this section are forward-looking statements.

We may be unable to protect our proprietary technology or may infringe on the proprietary technology of others.

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We have obtained U.S. patents and filed additional U.S. and foreign patent applications; however, there can be no assurance that any patents we hold, or for which we have applied, will provide us with any significant competitive advantages, that third parties will not challenge our patents, or that patents owned by others will not have an adverse effect on our ability to conduct business. We could incur substantial costs in preventing patent infringement, in curbing the unauthorized use of our proprietary technology by others, or in defending against similar claims of others. Since we rely on trade secrets and proprietary know-how to maintain our competitive position, there can be no assurance that others may not independently develop similar or superior technologies.

We operate in an increasingly competitive medical technology marketplace. There has also been substantial

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litigation regarding patent and other intellectual property rights in the medical device industry. Our activities may require us to defend against claims and actions alleging infringement of the intellectual property rights of others. If a court rules against us in any patent litigation, any of several negative outcomes could occur: we could be subject to significant liabilities, we could be forced to seek licenses from third parties, or we could be prevented from marketing certain products. Any of these outcomes could have a material adverse effect on our financial condition and operating results.

Our ability to remain competitive is dependent, in part, upon our ability to prevent other companies from using our proprietary technology incorporated into our products. We seek to protect our technology through a combination of patents, trademarks, and trade secrets, as well as licenses, proprietary know-how and confidentiality agreements. We may be unable, however, to prevent others from using our proprietary information, or continue to use such information our self, for numerous reasons, including the following, any of which could have a material adverse effect on our business, operations, or financial condition:

- Our issued patents may not be sufficiently broad to prevent others from copying our proprietary technologies
- Our issued patents may be challenged by third parties and deemed to be overbroad or unenforceable
- Our products may infringe on the patents or other intellectual property rights of other parties, requiring us to alter or discontinue our manufacture or sale of such products
- Costs associated with seeking enforcement of our patents against infringement, or defending our self against allegations of infringement, may be significant
- Our pending patent applications may not be granted for various reasons, including over breadth or conflict with an existing patent
- Other persons may independently develop, or have developed, similar or superior technologies

Economic and industry conditions constantly change, and negative economic conditions in the United States and other countries could materially and adversely affect our business and results of operations.

Our business and our results of operation are affected by many changing economic and other conditions beyond our control. Actual or potential changes in international, national, regional and local economic, business and financial conditions, including recession and inflation, may negatively affect consumer preferences, perceptions, spending patterns or demographic trends, any of which could adversely affect our business and results of operations. We may also experience higher bad-debt rates and slower receivable collection rates in our dealings with our

customers. In addition, recent disruptions in the credit markets have resulted in greater volatility, less liquidity, widening of credit spreads, and decreased availability of financing. As a result of these factors, there can be no assurance that financing will be available to us on acceptable terms, if at all. An inability to obtain necessary additional financing on acceptable terms may have an adverse impact on us and on our ability to grow our business.

Termination or interruption of relationships with our suppliers, or failure of such suppliers to perform, could disrupt our business.

We rely on raw materials, component parts, finished products, and services supplied by outside third parties in connection with our business. For example, substantially all of our products are sterilized by only a limited number of vendors. In addition, some of our products are manufactured or assembled by third parties. If a supplier of significant raw materials, component parts, finished goods, or services were to terminate its relationship with us, or otherwise cease supplying raw materials, component parts, finished goods, or services consistent with past practice, our ability to meet our obligations to our end customers may be disrupted. A disruption with respect to numerous products, or with respect to a few significant products, could have a material adverse effect on our business, operations or financial condition.

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Our products may be subject to recall or product liability claims.

Our products are used in connection with invasive procedures and in other medical contexts in which it is important that those products function with precision and accuracy. If our products do not function as designed, or are designed improperly, we may choose to or be forced by regulatory agencies to withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, or an inappropriate design, we could be subject to lawsuits seeking significant compensatory and punitive damages. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business, operations or financial condition.

We generally offer a limited warranty for product returns which are 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 or warranty obligations that exceed our historical experience, our financial condition and operating results could be materially and adversely affected.

We may be unable to successfully manage growth, particularly if accomplished through acquisitions.

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 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, 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.

To the extent that we grow through acquisition, we will face the additional challenges of integrating our current operations, culture, information management systems and other characteristics with that of the acquired entity. We may incur significant expenses in connection with negotiating and consummating one or more transactions, and we may inherit certain liabilities in connection with each acquisition. In addition, we may not realize competitive advantages, synergies or other benefits anticipated in connection with any such acquisition. If we do not adequately identify targets for, or manage issues related to, our future acquisitions, such acquisitions may have a negative adverse effect on our business and financial results.

A significant adverse change in, or failure to comply with, governing regulations could adversely affect our business.

Substantially all of our products are devices, as defined in the Federal Food, Drug and Cosmetic Act, and the manufacture, distribution, record keeping, labeling and advertisement of our products are subject to regulation by the FDA in the United States and its equivalent regulatory agencies in various foreign countries in which our products are manufactured, distributed, labeled, offered or sold. Further, we are subject to regular review and periodic inspections at our current facilities with respect to the FDA's Quality System Regulations and similar requirements of foreign countries. In addition, we are subject to certain export control restrictions governed by the U.S. Department of the Treasury and may be governed by other regulatory agencies in various foreign countries to which our products are exported. Although we believe we are currently in

material compliance with these requirements, any failure on our part to comply with all applicable current and future regulations could adversely affect our business, operations, or financial condition.

A significant portion of our revenues are derived from a few products, procedures and/or customers.

A significant portion of our revenues are attributable to sales of our inflation devices. During the year ended December 31, 2009, sales of our inflation devices (including inflation devices sold in custom kits and through OEM channels) accounted for approximately 24% of our total revenues. Sales of our inflation devices to a single OEM customer, representing our largest customer, were approximately 6% of our total inflation device sales for the year ended December 31, 2009. Any material decline in market demand, or change in OEM supplier preference, for our inflation devices could have an adverse effect on our business, operations or financial condition.

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In addition, the products that have accounted for a majority of our historical revenues are designed for use in connection with a few related medical procedures, including angioplasty, stent placement procedures, and spinal procedures. If subsequent developments in medical technology or drug therapy make such procedures obsolete, or alter the methodology of such procedures so as to eliminate the usefulness of our products, we may experience a material decrease in demand for our products and experience deteriorating financial performance.

We may be unable to compete in our markets, particularly if there is a significant change in relevant practices or technology.

The market for each of our products is highly competitive. We face competition from many companies which are larger, better established, have greater financial, technical and other resources and possess a greater market presence than we do. Such resources and market presence may enable our competition to more effectively market competing products or to market competing products at reduced prices in order to gain market share.

In addition, our ability to compete successfully is dependent, in part, upon our response to changes in technology and upon our efforts to develop and market new products which achieve significant market acceptance. Competing companies with substantially greater resources than us are actively engaged in research and development of new methods, treatments, drugs, and procedures to treat or prevent cardiovascular disease that could limit the market for our products and eventually make some of our products obsolete. A reduction in the demand for a significant number of our products, or a few key products, could have a material adverse effect on our business, operations or financial condition.

The market price of our common stock has been, and may continue to be, volatile.

The market price of our common stock has been, and may continue to be, volatile for various reasons, including the following, which could have a material adverse effect on our business, operations or financial condition:

- Our announcement of new products or technical innovations, or similar announcements by our competitors
- Development of new procedures that use, or do not use, our technology
- Quarter-to-quarter variances in our financial results
- Claims involving potential infringement of patents and other intellectual property rights

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- Analysts and other projections or recommendations regarding our common stock specifically or medical technology stocks generally
- Any restatement of our financial statements or any investigation of us by the SEC, the FDA or another regulatory authority
- A decline, or rise, of stock prices in the capital markets generally

Fluctuations in Euro and GBP exchange rates may negatively impact our financial results.

Our material market risk relates to fluctuations in the rate of exchange between the Euro and Great Britain Pound (GBP) relative to the value of the U.S. Dollar. Those fluctuations could have a negative impact on our margins and financial results. For example, during 2009, the exchange rate between those foreign currencies and the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$2.6 million and an increase of 0.10% in our gross profit.

For the year ended December 31, 2009, approximately \$26.3 million, or 10%, of our sales, were denominated in foreign currencies. If the rate of exchange between the Euro and the GBP declines, against the U.S. Dollar, we may not be able to increase the prices we charge our European customers for products whose prices are denominated in Euros and GBP. Furthermore, we may be unable or elect not to enter into hedging transactions which could mitigate the effect of declining exchange rates. As a result, if the rate of exchange between Euros and GBP declines, against the U.S. Dollar, our financial results may be negatively impacted.

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Operations at our manufacturing facilities may be negatively impacted by certain factors, including severe weather conditions and the impact of natural disasters.

Our operations could be affected by many factors beyond our control, including severe weather conditions and the impact of natural disasters, including hurricanes and tornados. These conditions could cause substantial damage to our facilities, interrupt our production and disrupt our ability to deliver products to our customers.

Our operations in Angleton, Texas have been suspended due to hurricanes in recent years. In September 2008 we shut down our operations in Angleton in anticipation of Hurricane Ike and production was restored shortly thereafter. While we incurred minimal damage to our facility, we experienced greater financial damage as a result of the production disruption. Although our insurance covered some of the losses associated with the event, future natural disasters could increase the cost of insurance. We cannot be certain that any losses from business interruption or property damages, along with the increases in insurance costs, will not have a material adverse effect on our results of operations or financial condition.

We are dependent upon key personnel.

Our success is dependent on key management personnel, including Fred P. Lampropoulos, our Chairman of the Board, President and Chief Executive Officer. Mr. Lampropoulos is not subject to any agreement prohibiting his departure, and we do not maintain key man life insurance on his life. The loss of Mr. Lampropoulos, or of certain other key management personnel, could have a materially adverse effect our business and operations. Our success also depends on, among other factors, the successful recruitment and retention of key operating, manufacturing, sales and other personnel.

We are subject to work stoppage, transportation and related risks.

We manufacture products at various locations in the United States and foreign countries and sell our products worldwide. We depend on third-party transportation companies to deliver supplies necessary to manufacture our products from vendors to our various facilities and to move our products to customers, operating divisions, and other subsidiaries located worldwide. Our manufacturing operations, and the operations of the transportation companies on which we depend, may be adversely affected by natural disasters or significant human events, such as a war, terrorist attack, riot, strike, slowdown or similar event. Any disruption in our manufacturing or transportation could materially adversely affect our ability to meet customer demands or our operations.

Limits on reimbursement imposed by governmental and other programs may adversely affect our business.

The cost of a significant portion of medical care is funded by governmental, social security or other insurance programs. Limits on reimbursement imposed by such programs may adversely affect the ability of hospitals and others to purchase our products. In addition, limitations on reimbursement for procedures which utilize our products could adversely affect sales.

Our failure to comply with applicable environmental laws and regulations could affect our business and results of operations.

Merit Sensor Systems, Inc., one of our wholly-owned subsidiaries, manufactures and assembles certain products that require the use of hazardous materials that are subject to various federal, state and local laws and regulations governing the protection of the environment. While the cost of compliance with such laws and regulations has not had a material adverse effect on our results of operations historically, compliance with future regulations may require additional capital investments in pollution control equipment or changes in the way Merit Sensor Systems makes its products. Additionally, because Merit Sensor Systems uses hazardous and other regulated materials in its manufacturing processes, we are subject to certain risks of liabilities and claims resulting from any accidental releases. While we believe the precautions and infrastructure Merit Sensor Systems has put in place are sufficient, any accidental release may have an adverse affect on our business and results of operations.

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Recently enacted health care reform legislation may adversely affect our business, financial condition, results of operations and cash flows.

As a result of recent legislation enacted in March of 2010, substantial changes are expected to occur in the United States health care system. The principal aim of the new regulations is to expand health insurance coverage to tens of millions of Americans. Extending coverage to such a large number of individuals could substantially change the structure of the U.S. health insurance system and the methodology could limit amounts paid to reimburse the purchase of medical devices, including our products. If reimbursement for our products is limited, our financial condition, results of operations and cash flows could be materially impacted.

The recently-enacted legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. A number of these provisions impose fees or taxes on medical device manufacturers. For example, beginning in 2013, medical device manufacturers will be required to pay an excise tax (or sales tax) in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. This tax applies to many medical devices, including many of our products. If we are required to pay additional taxes as a result of the new legislation, those payments will constitute additional expenses associated with the sale of each product, reducing the overall profit margin generated on the sale of such product and potentially adversely affecting our financial condition and results of operations.

In addition to the new legislation, the full effect of which is presently unknown given the legislation's recent enactment, various healthcare reform proposals have emerged at the state level. We cannot predict which of these initiatives, if any, will be implemented, or the effect any future legislation or regulation will have on us. Additionally, an expansion in the role of federal or state governments in the U.S. healthcare industry may lower reimbursements for our products, restrict coverage of certain medical devices (and, thereby, utilization) and/or generally reduce medical procedure volumes, any of which may adversely affect our business, financial condition and results of operations.

If our employees or agents violate the U.S. Foreign Corrupt Practices Act or anti-bribery laws in other jurisdictions, we may incur fines or penalties, or experience other adverse consequences.

We are subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery laws in non-U.S. jurisdictions which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents. If our employees or agents violate the provisions of the FCPA or other anti-bribery laws, we may incur fines or penalties, we may be unable to market our products in other countries or we may experience other adverse consequences which could have a material adverse effect on our operating results or financial condition.

We may be subject laws targeting fraud and abuse in the healthcare industry, the violation of which could adversely affect our business or financial results.

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Our operations are subject to various state and federal laws targeting fraud and abuse in the healthcare industry, including federal anti-kickback laws, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. Violations of these fraud and abuse-related laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States, any of which could adversely affect our business or financial results.

We may issue substantial amounts of additional shares without stockholder approval.

Our Articles of Incorporation authorize the issuance of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock, which may be issued without any action or approval by our shareholders. Any preferred shares issued would likely have preference over our common stock in various ways, which would be detailed at the time of such issuance. Subject to the provisions of our Articles of Incorporation, our board of directors has authority to issue these

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preferred shares at such time, in such amount, at such price, and with such preferences over our common stock, as it desires. In addition, we have stock option plans that have potential for diluting the ownership interests of our shareholders.

We have never declared a cash dividend and do not intend to declare a cash dividend in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We currently intend to retain any future earnings for use in our business and, therefore, do not anticipate paying dividends on our common stock in the foreseeable future. In addition, our revolving line of credit contains covenants prohibiting the declaration and distribution of a cash dividend at any time prior to the termination of such line of credit.

RATIO OF EARNINGS TO FIXED CHARGES

The following table presents the ratio of earnings to fixed charges of our company, which includes our subsidiaries, on a consolidated basis. We had no preferred stock outstanding for any period presented, and accordingly our ratio of earnings to combined fixed charges and preferred stock dividends is the same as our ratio of earnings to fixed charges. For purposes of computing the ratio of earnings to fixed charges, earnings were calculated by adding (1) pre-tax earnings from continuing operations; and (2) fixed charges. Fixed charges consist of the sum of (1) interest expense on long-term and short-term debt; and (2) estimated interest within rental expense.

Nine Months Ended September 30,

Year Ended December 31,