

MERIT MEDICAL SYSTEMS INC

Form 10-Q

November 09, 2016

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM                      TO                      .

Commission File Number 0-18592

MERIT MEDICAL SYSTEMS, INC.

(Exact name of Registrant as specified in its charter)

Utah

87-0447695

(State or other jurisdiction of incorporation or organization) (I.R.S. Identification No.)

1600 West Merit Parkway, South Jordan, UT, 84095

(Address of Principal Executive Offices, including Zip Code)

(801) 253-1600

(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definition 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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date.

Common Stock 44,587,038

| Title or class | Number of Shares<br>Outstanding at November 4, 2016 |
|----------------|---|
|----------------|---|

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## PART I - FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED BALANCE SHEETS  
 SEPTEMBER 30, 2016 AND DECEMBER 31, 2015  
 (In thousands)

|   | September<br>30, 2016 | December<br>31, 2015 |
|---|-----------------------|----------------------|
| ASSETS  |                       | (unaudited)          |
| CURRENT ASSETS:   |                       |                      |
| Cash and cash equivalents   | \$ 17,318             | \$ 4,177             |
| Trade receivables — net of allowance for uncollectible accounts — 2016 — \$1,731 and 2015 — \$1,731 | 79,507                | 70,292               |
| Employee receivables  | 176                   | 217                  |
| Other receivables   | 3,350                 | 6,799                |
| Inventories   | 116,908               | 105,999              |
| Prepaid expenses  | 7,005                 | 5,634                |
| Prepaid income taxes  | 3,059                 | 2,955                |
| Deferred income tax assets  | 6,408                 | 7,025                |
| Income tax refund receivables   | 373                   | 905                  |
| Total current assets  | 234,294               | 204,003              |
| PROPERTY AND EQUIPMENT:   |                       |                      |
| Land and land improvements  | 19,539                | 19,307               |
| Buildings   | 139,559               | 136,595              |
| Manufacturing equipment   | 171,308               | 158,775              |
| Furniture and fixtures  | 43,425                | 39,301               |
| Leasehold improvements  | 29,519                | 27,561               |
| Construction-in-progress  | 33,073                | 26,292               |
| Total property and equipment  | 436,423               | 407,831              |
| Less accumulated depreciation   | (157,797 )            | (140,053 )           |
| Property and equipment — net  | 278,626               | 267,778              |
| OTHER ASSETS:   |                       |                      |
| Intangible assets:  |                       |                      |
| Developed technology — net of accumulated amortization — 2016 — \$48,546 and 2015 — \$48,546        | 38,963                | 69,861               |
| Other — net of accumulated amortization — 2016 — \$28,441 and 2015 — \$26,603                       | 46,701                | 39,493               |
| Goodwill  | 213,069               | 184,472              |
| Other assets  | 16,296                | 13,121               |
| Total other assets  | 415,679               | 306,947              |

|       |           |           |
|-------|-----------|-----------|
| TOTAL | \$928,599 | \$778,728 |
|-------|-----------|-----------|

See condensed notes to consolidated financial statements. (continued)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
SEPTEMBER 30, 2016 AND DECEMBER 31, 2015  
(In thousands)

|   | September<br>30, 2016 | December<br>31, 2015 |
|---|-----------------------|----------------------|
| (unaudited)   |                       |                      |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |                       |                      |
| CURRENT LIABILITIES:  |                       |                      |
| Trade payables  | \$ 30,192             | \$ 37,977            |
| Accrued expenses  | 44,927                | 37,846               |
| Current portion of long-term debt   | 10,000                | 10,000               |
| Advances from employees   | 544                   | 589                  |
| Income taxes payable  | 809                   | 1,498                |
| Total current liabilities   | 86,472                | 87,910               |
| LONG-TERM DEBT  | 317,760               | 197,593              |
| DEFERRED INCOME TAX LIABILITIES   | 21,886                | 10,985               |
| LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS  | 402                   | 768                  |
| DEFERRED COMPENSATION PAYABLE   | 9,000                 | 8,500                |
| DEFERRED CREDITS  | 2,593                 | 2,721                |
| OTHER LONG-TERM OBLIGATIONS   | 4,546                 | 4,148                |
| Total liabilities   | 442,659               | 312,625              |
| COMMITMENTS AND CONTINGENCIES (Notes 5, 9, 10, and 13)  |                       |                      |
| STOCKHOLDERS' EQUITY:   |                       |                      |
| Preferred stock — 5,000 shares authorized as of September 30, 2016 and December 31, 2015;<br>no shares issued                                       |                       |                      |
| Common stock, no par value; shares authorized — 100,000; issued and outstanding as of<br>September 30, 2016 - 44,587 and December 31, 2015 - 44,267 | 204,601               | 197,826              |
| Retained earnings   | 286,378               | 273,764              |
| Accumulated other comprehensive loss  | (5,039                | ) (5,487 )           |
| Total stockholders' equity  | 485,940               | 466,103              |
| TOTAL   | \$ 928,599            | \$ 778,728           |
| See condensed notes to consolidated financial statements.   |                       | (concluded)          |



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015  
(In thousands, except per share amounts - unaudited)

|  | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|--|-------------------------------------|-----------|------------------------------------|-----------|
|  | 2016                                | 2015      | 2016                               | 2015      |
| NET SALES                                    | \$156,975                           | \$136,086 | \$446,123                          | \$403,745 |
| COST OF SALES                                | 89,160                              | 76,881    | 251,354                            | 228,271   |
| GROSS PROFIT                                 | 67,815                              | 59,205    | 194,769                            | 175,474   |
| OPERATING EXPENSES:                          |                                     |           |                                    |           |
| Selling, general and administrative          | 53,198                              | 39,201    | 138,556                            | 115,407   |
| Research and development                     | 11,424                              | 10,515    | 33,440                             | 29,389    |
| Contingent consideration (benefit) expense   | (94                                 | ) (58     | ) 99                               | 185       |
| Acquired in-process research and development | 300                                 | 1,000     | 400                                | 1,000     |
| Total operating expenses                     | 64,828                              | 50,658    | 172,495                            | 145,981   |
| INCOME FROM OPERATIONS                       | 2,987                               | 8,547     | 22,274                             | 29,493    |
| OTHER INCOME (EXPENSE):                      |                                     |           |                                    |           |
| Interest income                              | 29                                  | 78        | 55                                 | 210       |
| Interest expense                             | (3,022                              | ) (1,489  | ) (6,120                           | ) (4,776  |
| Other income (expense) — net                 | 1                                   | (476      | ) (445                             | ) (281    |
| Other expense — net                          | (2,992                              | ) (1,887  | ) (6,510                           | ) (4,847  |
| INCOME (LOSS) BEFORE INCOME TAXES            | (5                                  | ) 6,660   | 15,764                             | 24,646    |
| INCOME TAX EXPENSE (BENEFIT)                 | (978                                | ) 1,842   | 3,149                              | 7,253     |
| NET INCOME                                   | \$973                               | \$4,818   | \$12,615                           | \$17,393  |
| EARNINGS PER COMMON SHARE:                   |                                     |           |                                    |           |
| Basic  | \$0.02                              | \$0.11    | \$0.28                             | \$0.40    |
| Diluted                                      | \$0.02                              | \$0.11    | \$0.28                             | \$0.39    |
| AVERAGE COMMON SHARES:                       |                                     |           |                                    |           |
| Basic  | 44,447                              | 44,165    | 44,346                             | 43,976    |
| Diluted                                      | 45,000                              | 44,734    | 44,763                             | 44,467    |

See condensed notes to consolidated financial statements.





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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015  
 (In thousands - unaudited)

|   | Three Months<br>Ended<br>September 30,<br>2016 |         | Nine Months<br>Ended September<br>30,<br>2015 |          |
|---|--|---------|---|----------|
| Net income                              | \$973  | \$4,818 | \$12,615                                      | \$17,393 |
| Other comprehensive income (loss):      |  |         |   |          |
| Interest rate swap                      | (103 )   | (621 )  | (984 )  | (1,421 ) |
| Less income tax benefit                 | 40   | 242     | 383   | 553      |
| Foreign currency translation adjustment | 454  | (497 )  | 1,259   | (2,106 ) |
| Less income tax benefit (expense)       | —  | 185     | (210 )  | 258      |
| Total other comprehensive income (loss) | 391  | (691 )  | 448   | (2,716 ) |
| Total comprehensive income              | \$1,364  | 4,127   | \$13,063                                      | \$14,677 |

See condensed notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF CASH FLOWS  
 FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015  
 (In thousands - unaudited)

|   | Nine<br>Months<br>Ended<br>September<br>30,<br>2015 |
|---|---|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                      |   |
| Net income  | 12,617,393  |
| Adjustments to reconcile net income to net cash provided by operating activities: |   |
| Depreciation and amortization   | 3,125,974   |
| Losses on sales and/or abandonment of property and equipment                      | 10,221  |
| Write-off of patents and intangible assets  | 9,099   |
| Acquired in-process research and development                                      | 400,000   |
| Fair value changes in contingent liabilities/assets                               | 99—   |
| Amortization of deferred credits  | <del>(1,082,9</del> )                               |
| Amortization of long-term debt issuance costs                                     | 77,741  |
| Deferred income taxes   | 18,756  |
| Excess tax benefits from stock-based compensation                                 | <del>(5,017,972</del> )                             |
| Stock-based compensation expense  | 1,916,433   |
| Changes in operating assets and liabilities, net of effects from acquisitions:    |   |
| Trade receivables   | <del>(5,166,24</del> )                              |
| Employee receivables  | 42,37 )   |
| Other receivables   | 3,386   |
| Inventories   | 220,432 )   |
| Prepaid expenses  | <del>(46,099</del> )                                |
| Prepaid income taxes  | <del>(6,043</del> )                                 |
| Income tax refund receivables   | 51,218 )  |
| Other assets  | <del>(1,596</del> )                                 |
| Trade payables  | <del>(9,0788</del> )                                |
| Accrued expenses  | 1,693,17  |
| Advances from employees   | <del>(5,064</del> )                                 |
| Income taxes payable  | <del>(18,046</del> )                                |
| Liabilities related to unrecognized tax benefits                                  | <del>(3,604</del> )                                 |
| Deferred compensation payable   | 50,098  |
| Other long-term obligations   | <del>(2,602</del> )                                 |
| Total adjustments   | 23,392,312  |
| Net cash provided by operating activities   | 36,330,5  |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                      |   |
| Capital expenditures for:   |   |
| Property and equipment  | <del>(2,699,01</del> )                              |
| Intangible assets   | <del>(1,598,5</del> )                               |

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|   |                      |
|---|----------------------|
| Proceeds from sale-leaseback transactions                 | —2,017               |
| Proceeds from the sale of property and equipment          | 5 42                 |
| Proceeds from sale of cost method investment              | 1,089                |
| Cash paid in acquisitions, net of cash acquired           | <del>(10,808 )</del> |
| Net cash used in investing activities                     | <del>(10,805 )</del> |
| See condensed notes to consolidated financial statements. | (continued)          |

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015  
(In thousands - unaudited)

|  | Nine Months<br>Ended<br>September 30, |            |
|--|---------------------------------------|------------|
|  | 2016                                  | 2015       |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |                                       |            |
| Proceeds from issuance of common stock   | \$4,422                               | \$ 5,924   |
| Proceeds from issuance of long-term debt   | 203,478                               | 109,905    |
| Payments on long-term debt   | (82,658 )                             | (124,177 ) |
| Excess tax benefits from stock-based compensation  | 527                                   | 1,972      |
| Long-term debt issuance costs  | (1,948 )                              | —          |
| Contingent payments related to acquisitions  | (199 )                                | (194 )     |
| Payment of taxes related to an exchange of common stock  | (86 )                                 | (918 )     |
| Net cash provided by (used in) financing activities  | 123,536                               | (7,488 )   |
| <b>EFFECT OF EXCHANGE RATES ON CASH</b>  | 67                                    | (318 )     |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>  | 13,141                                | (1,496 )   |
| <b>CASH AND CASH EQUIVALENTS:</b>  |                                       |            |
| Beginning of period  | 4,177                                 | 7,355      |
| End of period  | \$17,318                              | \$ 5,859   |
| <b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>   |                                       |            |
| Cash paid during the period for:   |                                       |            |
| Interest (net of capitalized interest of \$337 and \$256, respectively)                                    | \$6,223                               | \$ 4,713   |
| Income taxes   | \$2,237                               | \$ 2,905   |
| <b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>                              |                                       |            |
| Property and equipment purchases in accounts payable   | \$2,709                               | \$ 2,321   |
| Cost method investment converted to intangible asset in acquisition in lieu of additional cash payment     | \$—                                   | \$ 1,010   |
| Contingent receivable received in exchange for sale of cost method investment                              | \$711                                 | \$—        |
| Acquisition purchases in accrued expenses and other long-term obligations                                  | \$293                                 | \$ 1,300   |
| Merit common stock surrendered (14 and 185 shares, respectively) in exchange for exercise of stock options | \$346                                 | \$ 3,802   |
| See condensed notes to consolidated financial statements.  | (concluded)                           |            |



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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES  
 CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 (Unaudited)

1. Basis of Presentation. The interim consolidated financial statements of Merit Medical Systems, Inc. ("Merit," "we" or "us") for the three and nine-month periods ended September 30, 2016 and 2015 are not audited. Our consolidated financial statements are prepared in accordance with the requirements for unaudited interim periods and, consequently, do not include all disclosures required to be made in conformity with accounting principles generally accepted in the United States of America. In the opinion of our management, the accompanying consolidated financial statements contain all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial position as of September 30, 2016 and December 31, 2015, and our results of operations and cash flows for the three and nine-month periods ended September 30, 2016 and 2015. The results of operations for the three and nine-month periods ended September 30, 2016 and 2015 are not necessarily indicative of the results for a full-year period. These interim consolidated financial statements should be read in conjunction with the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission (the "SEC").

2. Inventories. Inventories at September 30, 2016 and December 31, 2015 consisted of the following (in thousands):

|                 | September<br>30,<br>2016 | December<br>31,<br>2015 |
|-----------------|--------------------------|-------------------------|
| Finished goods  | \$ 57,114                | \$ 59,170               |
| Work-in-process | 14,662                   | 8,540                   |
| Raw materials   | 45,132                   | 38,289                  |
| Total           | \$ 116,908               | \$ 105,999              |

3. Stock-Based Compensation. Stock-based compensation expense before income tax expense for the three and nine-month periods ended September 30, 2016 and 2015, consisted of the following (in thousands):

|   | Three<br>Months<br>Ended<br>September<br>30,<br>2016 |        | Nine Months<br>Ended<br>September 30,<br>2015 |          |
|---|--|--------|---|----------|
| Cost of goods sold                            | \$ 105   | \$ 84  | \$ 369  | \$ 285   |
| Research and development                      | 51   | 35     | 147   | 94       |
| Selling, general and administrative           | 347  | 439    | 1,397   | 1,264    |
| Stock-based compensation expense before taxes | \$ 503   | \$ 558 | \$ 1,913                                      | \$ 1,643 |

As of September 30, 2016, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$8.0 million and is expected to be recognized over a weighted average period of 3.61 years.

During the three and nine-month periods ended September 30, 2016, we granted awards representing 21,000 and 805,375 shares of our common stock, respectively. During the three and nine-month periods ended September 30, 2015, we granted awards representing 21,233 and 618,033 shares of our common stock, respectively. We use the Black-Scholes methodology to value the stock-based compensation expense for options. In applying the

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Black-Scholes methodology to the options granted during the nine-month periods ended September 30, 2016 and 2015, the fair value of our stock-based awards granted was estimated using the following assumptions for the periods indicated below:

|                           | Nine months ended September 30, |                 |
|---------------------------|---------------------------------|-----------------|
|                           | 2016                            | 2015            |
| Risk-free interest rate   | 1.15% - 1.40%                   | 1.53% - 1.66%   |
| Expected option life      | 5.0                             | 5.0             |
| Expected dividend yield   | —%                              | —%              |
| Expected price volatility | 36.30% - 37.06%                 | 33.72% - 35.11% |

For purposes of the foregoing analysis, the average risk-free interest rate is determined using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. The expected term of the stock options is determined using the



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historical exercise behavior of employees. The expected price volatility is determined using a weighted average of daily historical volatility of our stock price over the corresponding expected option life and implied volatility based on recent trends of the daily historical volatility. Compensation expense is recognized on a straight-line basis over the service period, which corresponds to the related vesting period.

4. Earnings Per Common Share (EPS). The computation of weighted average shares outstanding and the basic and diluted earnings per common share for the following periods consisted of the following (in thousands, except per share amounts):

|   | Three Months |        |                  | Nine Months |        |                  |
|---|--------------|--------|------------------|-------------|--------|------------------|
|   | Net Income   | Shares | Per Share Amount | Net Income  | Shares | Per Share Amount |
| Period ended September 30, 2016:  |              |        |                  |             |        |                  |
| Basic EPS   | \$973        | 44,447 | \$ 0.02          | \$12,615    | 44,346 | \$0.28           |
| Effect of dilutive stock options and warrants   |              | 553    |                  |             | 417    |                  |
| Diluted EPS   | \$973        | 45,000 | \$ 0.02          | \$12,615    | 44,763 | \$0.28           |
| Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive |              | 408    |                  |             | 864    |                  |
| Period ended September 30, 2015:  |              |        |                  |             |        |                  |
| Basic EPS   | \$4,818      | 44,165 | \$ 0.11          | \$17,393    | 43,976 | \$ 0.40          |
| Effect of dilutive stock options and warrants   |              | 569    |                  |             | 491    |                  |
| Diluted EPS   | \$4,818      | 44,734 | \$ 0.11          | \$17,393    | 44,467 | \$ 0.39          |
| Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive |              | 168    |                  |             | 468    |                  |

5. Acquisitions and Strategic Investments. On July 6, 2016, we consummated the transactions contemplated by an Agreement and Plan of Merger by and among Merit, MMS Transaction Co., a wholly-owned subsidiary of Merit, DFINE Inc. ("DFINE"), certain preferred stockholders of DFINE and Shareholder Representative Services LLC, as a stockholder representative, and acquired all of the issued and outstanding shares of DFINE (the "Acquisition"). We made an initial payment of \$97.5 million to certain DFINE stockholders on July 6, 2016 and paid approximately \$578,000 related to a net working capital adjustment subject to review by Merit and the preferred stockholders of DFINE. We accounted for the Acquisition as a business combination. Acquisition-related costs during the three and nine-month periods ended September 30, 2016, which are included in selling, general, and administrative expenses in the consolidated statements of income, were approximately \$1.6 million. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. Our consolidated financial statements for the three and nine months ended September 30, 2016 include approximately \$7.0 million of net sales related to the acquisition. It is not practical to separately report the earnings related to the Acquisition, as we cannot split out sales costs related to DFINE products, principally because our sales representatives are selling multiple products (including DFINE products) in the cardiovascular business segment. The purchase price was preliminarily allocated to the net tangible and intangible assets acquired and liabilities assumed, based on available information, as follows (in thousands):



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|                        |         |
|------------------------|---------|
| Assets Acquired        |         |
| Trade receivables      | 4,054   |
| Other receivables      | 6       |
| Inventories            | 8,674   |
| Prepaid expenses       | 630     |
| Property and equipment | 1,739   |
| Other long-term assets | 145     |
| Intangibles            |         |
| Developed technology   | 67,600  |
| Customer lists         | 2,400   |
| Trademarks             | 4,400   |
| Goodwill               | 26,029  |
| Total assets acquired  | 115,677 |

|  |           |
|--|-----------|
| Liabilities Assumed                          |           |
| Trade payables                               | (1,790 )  |
| Accrued expenses                             | (5,705 )  |
| Deferred income tax liabilities - current    | (603 )    |
| Deferred income tax liabilities - noncurrent | (10,829 ) |
| Total liabilities assumed                    | (18,927 ) |

Net assets acquired, net of cash received of \$1,327 96,750

The gross amount of trade receivables we acquired in the Acquisition was approximately \$4.3 million, of which approximately \$224,000 was expected to be uncollectible. With respect to the DFINE assets, we intend to amortize developed technology over fifteen years and customer lists on an accelerated basis over nine years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of fifteen years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 14.8 years.

The following table summarizes our unaudited consolidated results of operations for the three and nine-month periods ended September 30, 2015, as well as unaudited pro forma consolidated results of operations as though the Acquisition had occurred on January 1, 2015 (in thousands, except per common share amounts):

|                            | Three Months       |                    | Nine Months Ended  |                    |
|----------------------------|--------------------|--------------------|--------------------|--------------------|
|                            | Ended              |                    | September 30, 2015 |                    |
|                            | September 30, 2015 | September 30, 2015 | September 30, 2015 | September 30, 2015 |
|                            | As Reported        | Pro Forma          | As Reported        | Pro Forma          |
| Net Sales                  | \$136,086          | \$144,344          | \$403,745          | \$428,881          |
| Net Income                 | 4,818              | 673                | 17,393             | 5,190              |
| Earnings per common share: |                    |                    |                    |                    |
| Basic                      | \$0.11             | \$0.02             | \$0.40             | \$0.12             |
| Diluted                    | \$0.11             | \$0.02             | \$0.39             | \$0.12             |

On February 4, 2016, we purchased the HeRO® Graft device and other related assets from CryoLife, Inc., a developer of medical devices based in Kennesaw, Georgia ("CryoLife"). The purchase price was \$18.5 million, which was paid in full during the first quarter of 2016. We accounted for this acquisition as a business combination. The purchase price was allocated as follows (in thousands):

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## Assets Acquired

|              |       |
|--------------|-------|
| Inventories  | 2,455 |
| Fixed Assets | 290   |

## Intangibles

|                      |        |
|----------------------|--------|
| Developed Technology | 12,100 |
| Trademarks           | 700    |
| Customer Lists       | 400    |
| Goodwill             | 2,555  |

Total assets acquired 18,500

We are amortizing the developed HeRO Graft technology asset over ten years, the related trademarks over 5.5 years, and the associated customer lists over 12 years. We have estimated the weighted average life of the intangible HeRO Graft assets acquired to be approximately 9.82 years. Acquisition-related costs related to the HeRO Graft device and other related assets during the nine months ended September 30, 2016, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were not material. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the three and nine-month periods ended September 30, 2016, our net sales of the products acquired from CryoLife were approximately \$1.9 million and \$5.2 million, respectively. It is not practical to separately report the earnings related to the products acquired from CryoLife, as we cannot split out sales costs related to those products, principally because our sales representatives are selling multiple products (including the HeRO Graft device) in the cardiovascular business segment. The pro forma consolidated results of operations acquired from CryoLife are not presented, as we believe the pro forma financial effect of the transaction is not material.

On January 20, 2016, we paid \$2.0 million for 2.0 million preferred limited liability company units of Cagent Vascular, LLC, a medical device company ("Cagent"). During the three months ended June 30, 2016, we paid \$500,000 for an additional 500,000 preferred limited liability company units of Cagent. Our total purchase price paid for the Cagent preferred limited liability company units as of September 30, 2016, which represents an ownership interest of approximately 18.6% of Cagent, has been accounted for at cost.

On December 4, 2015, we entered into a license agreement with ArraVasc Limited, an Irish medical device company, for the right to manufacture and sell certain percutaneous transluminal angioplasty balloon catheter products. As of December 31, 2015, we had paid \$500,000 pursuant to the terms of the license agreement. During the nine-month period ended September 30, 2016, we paid an additional \$1.25 million as certain milestones set forth in the license agreement were met during that period. We are obligated to pay an additional \$250,000 if additional milestones set forth in the license agreement are reached. We accounted for the transaction as an asset purchase and intend to amortize the license agreement intangible asset over a period of 12 years.

On July 14, 2015, we entered into an asset purchase agreement with Quellent, LLC, a California limited liability company ("Quellent"), for superabsorbent pad technology. The purchase price for the asset was \$1.0 million, payable in two installments. We accounted for this acquisition as a business combination. The first payment of \$500,000 was paid as of December 31, 2015, and the second payment of \$500,000 was recorded as an accrued liability as of December 31, 2015 and paid in the first quarter of 2016. We also recorded \$270,000 of contingent consideration related to royalties payable to Quellent pursuant to the asset purchase agreement as of December 31, 2015. The sales and results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date and were not material. The purchase price was allocated as follows: \$1.21 million to a developed technology intangible asset and \$60,000 to goodwill as of December 31, 2015. We are amortizing the developed technology intangible asset over 13 years. The pro forma consolidated results of operations are not presented, as we

believe the pro forma financial effect of the transaction is not material.

The goodwill arising from the acquisitions discussed above consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets and operations with our historical operations (see Note 12). The goodwill recognized from these acquisitions is expected to be deductible for income tax purposes.

6. Segment Reporting. We report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management ("CRM"), electrophysiology ("EP"), and interventional oncology and spine devices. Our endoscopy segment consists of gastroenterology and pulmonology medical device products which assist in the palliative treatment of expanding esophageal,

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tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income.

Financial information relating to our reportable operating segments and reconciliations to the consolidated totals for the three and nine-month periods ended September 30, 2016 and 2015 are as follows (in thousands):

|                         | Three Months<br>Ended September<br>30, |           | Nine Months Ended<br>September 30, |           |
|-------------------------|--|-----------|------------------------------------|-----------|
|                         | 2016                                   | 2015      | 2016                               | 2015      |
| <b>Revenues</b>         |  |           |                                    |           |
| Cardiovascular          | \$150,599                              | \$130,957 | \$428,668                          | \$388,507 |
| Endoscopy               | 6,376                                  | 5,129     | 17,455                             | 15,238    |
| Total revenues          | \$156,975                              | \$136,086 | \$446,123                          | \$403,745 |
| <b>Operating income</b> |  |           |                                    |           |
| Cardiovascular          | \$1,954                                | \$7,995   | \$19,482                           | \$27,323  |
| Endoscopy               | 1,033                                  | 552       | 2,792                              | 2,170     |
| Total operating income  | \$2,987                                | \$8,547   | \$22,274                           | \$29,493  |

7. Recent Accounting Pronouncements. In October 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. ASU 2016-16 will be effective for us on January 1, 2018. We are currently evaluating the impact of adopting ASU 2016-16 on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 will be effective for us on January 1, 2018 with early adoption permitted. We are assessing the impact that ASU 2016-15 is anticipated to have on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires companies to record excess tax benefits and deficiencies in income rather than the current requirement to record them through equity. ASU 2016-09 also allows companies the option to recognize forfeitures of share-based awards when they occur rather than the current requirement to make an estimate upon the grant of the awards. ASU 2016-09 will be effective for us on January 1, 2017. Early adoption of ASU 2016-09 will be permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. We are assessing the impact that ASU 2016-09 is anticipated to have on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which eliminates the current tests for lease classification under U.S. GAAP and requires lessees to recognize the right-of-use assets and related lease liabilities on the balance sheet for all leases greater than one year in duration. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. ASU 2016-02 provides that lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective

approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. We are assessing the impact that ASU 2016-02 is anticipated to have on our consolidated financial statements, and we currently expect that most of our operating lease commitments will be subject to the new standard and recognized as lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities, which amends the guidance regarding the classification and measurement of financial instruments. Changes to the current guidance primarily affect the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, ASU 2016-01 clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. ASU 2016-01 will be effective for us on January 1, 2018. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit

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risk in other comprehensive income. Upon adoption of ASU 2016-01, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. We do not presently anticipate that the adoption of ASU 2016-01 will have a material impact on our financial statements.

In November 2015, the FASB issued Accounting Standards Update ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which will require deferred tax assets and deferred tax liabilities to be presented as noncurrent within a classified balance sheet. ASU 2015-17 simplifies the current guidance which requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified balance sheet. The current requirement that deferred tax assets and liabilities of a tax-paying component of an entity be offset and presented as a single amount is not affected. ASU 2015-17 will be effective for us as of January 1, 2017 with early application permitted. ASU 2015-17 may be applied either prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. We have elected not to early adopt ASU 2015-17, and we are evaluating whether to apply the provisions prospectively or retrospectively upon adoption. We do not presently anticipate that the adoption of ASU 2015-17 will have a material impact on our financial statements.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory. ASU 2015-11 requires that inventory be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Inventory measured using last-in, first-out or the retail inventory method are excluded from the scope of ASU 2015-11 which is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We do not anticipate that the implementation of ASU 2015-11 will have a material impact on our consolidated financial statements.

In May 2014, the FASB issued authoritative guidance amending the FASB Accounting Standards Codification and creating a new Topic 606, Revenue from Contracts with Customers. The new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP applicable to revenue transactions. This guidance provides that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The existing industry guidance will be eliminated when the new guidance becomes effective and annual disclosures will be substantially revised. Additional disclosures will also be required under the new standard. In July 2015, the FASB approved a proposal that extended the required implementation date one year to the first quarter of 2018 but also would permit companies to adopt the standard at the original effective date of January 1, 2017. The FASB has issued several updates to the standard which (i) clarify the application of the principal versus agent guidance (ASU 2016-08); (ii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10) and (iii) narrow scope improvements and practical expedients (ASU 2016-12). Implementation of the new standard may be either through retrospective application to each period from the first quarter of 2016 or with a cumulative effect adjustment upon adoption in 2018. We are assessing the impact this new standard is anticipated to have on our consolidated financial statements.

8. Income Taxes. Our provision for income taxes for the three months ended September 30, 2016 was a tax benefit of approximately \$978,000, compared to a tax expense of approximately \$1.8 million for the corresponding period of 2015. The income tax benefit recorded during the third quarter of 2016 was primarily due to a decrease in the estimated annual effective tax rate and certain discrete tax benefits recorded during the quarter. The decrease in the estimated annual effective tax rate was due primarily to shifts in the projected mix of earnings by jurisdiction during the three-month period ended September 30, 2016. The discrete tax benefits recorded during the quarter ended September 30, 2016 were primarily related to the release of certain liabilities related to unrecognized tax benefits due to statute of limitation expirations and favorable adjustments to research and development tax credits.



Our provision for income taxes for the nine months ended September 30, 2016 and 2015 was a tax expense of approximately \$3.1 million and a tax expense of approximately \$7.3 million, respectively, which resulted in an effective tax rate of 20.0% and 29.4%, respectively. The decrease in the effective income tax rate for the nine-month period ended September 30, 2016, when compared to the corresponding period of 2015, was primarily related to shifts in our projected mix of earnings by jurisdiction during the three-month period ended September 30, 2016.

9. Long-term Debt. On July 6, 2016, we entered into a Second Amended and Restated Credit Agreement (the “Second Amended Credit Agreement”), with Wells Fargo Bank, National Association, as administrative agent (the “Agent”), swingline lender and a lender, and Wells Fargo Securities, LLC, as sole lead arranger and sole bookrunner. In addition to Wells Fargo Bank, National Association, Bank of America, N.A., U.S. Bank, National Association, and HSBC Bank USA, National Association, are parties to the Second Amended Credit Agreement as lenders. The Second Amended Credit Agreement amends and restates in its entirety Merit’s previously outstanding Amended and Restated Credit Agreement and all amendments thereto.

The Second Amended Credit Agreement provides for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$275 million, which includes a reserve of \$25 million to make swingline loans from time to time. The term

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loan is payable in quarterly installments in the amounts provided in the Second Amended Credit Agreement until the maturity date of July 6, 2021, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans, term loans, and all swingline loans in whole or in part, subject to certain minimum thresholds, without premium or penalty, other than breakage costs.

In summary, principal balances under our long-term debt as of September 30, 2016 and December 31, 2015, consisted of the following (in thousands):

|                                 | September<br>30, 2016 | December<br>31, 2015 |
|---------------------------------|-----------------------|----------------------|
| Term loan                       | \$ 147,500            | \$ 64,962            |
| Revolving credit loans          | 180,913               | 142,631              |
| Less debt issuance costs (653 ) | —                     | —                    |
| Total long-term debt            | 327,760               | 207,593              |
| Less current portion            | 10,000                | 10,000               |
| Long-term portion               | \$ 317,760            | \$ 197,593           |

Revolving credit loans denominated in dollars and term loans made under the Second Amended Credit Agreement bear interest, at our election, at either a Base Rate or Eurocurrency Base Rate (as such terms are defined in the Second Amended Credit Agreement) plus the applicable margin, which increases as our Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) increases. Revolving credit loans denominated in an Alternative Currency (as defined in the Second Amended Credit Agreement) bear interest at the Eurocurrency rate plus the applicable margin. Swingline loans bear interest at the base rate plus the applicable margin. Upon an event of default, the interest rate may be increased by 2.0%. The revolving credit commitment will also carry a commitment fee of 0.15% to 0.4% per annum on the unused portion.

The Second Amended Credit Agreement is collateralized by substantially all our assets. The Second Amended Credit Agreement contains covenants, representations and warranties and other terms customary for loans of this nature. The Second Amended Credit Agreement requires that we maintain certain financial covenants, as follows:

|  | Covenant Requirement |
|--|----------------------|
| Consolidated Total Leverage Ratio (1)  |                      |
| Through March 31, 2017                 | 4.5 to 1.0           |
| April 1, 2017 through June 30, 2017    | 4.0 to 1.0           |
| July 1, 2017 through December 31, 2017 | 3.75 to 1.0          |
| January 1, 2018 through March 31, 2018 | 3.5 to 1.0           |
| April 1, 2018 and thereafter           | 3.25 to 1.0          |
| Consolidated EBITDA (2)                | 1.25 to 1.0          |
| Consolidated Net Income (3)            | \$—                  |
| Facility Capital Expenditures (4)      | \$30 million         |

(1) Maximum Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) as of any fiscal quarter end.

(2) Minimum ratio of Consolidated EBITDA (as defined in the Second Amended Credit Agreement and adjusted for certain expenditures) to Consolidated Fixed Charges (as defined in the Second Amended Credit Agreement) for any period of four consecutive fiscal quarters.

(3) Minimum level of Consolidated Net Income (as defined in the Second Amended Credit Agreement) for certain periods, and subject to certain adjustments.

Maximum level of the aggregate amount of all Facility Capital  
(4) Expenditures (as defined in the Second Amended Credit  
Agreement) in any fiscal year.

Additionally, the Second Amended Credit Agreement contains customary events of default and affirmative and negative covenants for transactions of this type. As of September 30, 2016, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

Future minimum principal payments on our long-term debt as of September 30, 2016, are as follows (in thousands):

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| Years Ending                            | Future<br>Minimum<br>Principal<br>Payments |
|---|--|
| December 31                             |  |
| 2016                                    | 2,500                                      |
| 2017                                    | 10,000                                     |
| 2018                                    | 12,500                                     |
| 2019                                    | 15,000                                     |
| 2020                                    | 17,500                                     |
| Thereafter                              | 270,913                                    |
| Total future minimum principal payments | \$ 328,413                                 |

As of September 30, 2016, we had outstanding borrowings of approximately \$328.4 million under the Second Amended Credit Agreement, with available borrowings of approximately \$91.6 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of September 30, 2016 was a fixed rate of 3.48% on \$131.3 million and 3.62% on \$43.8 million as a result of interest rate swaps (see Note 10), a variable floating rate of 3.02% on \$153.0 million and a variable floating rate of 5.00% on approximately \$0.4 million. Our interest rate as of December 31, 2015 was a fixed rate of 2.48% on \$135.0 million as a result of an interest rate swap, a variable floating rate of 1.74% on \$65.8 million and a variable floating rate of 2.12% on approximately \$6.8 million.

## 10. Derivatives.

**Interest Rate Swap.** A portion of our debt bears interest at variable interest rates and, therefore, we are subject to variability in the cash paid for interest expense. In an effort to mitigate a portion of this risk, we use a hedging strategy to reduce the variability of cash flows in the interest payments associated with a portion of the variable-rate debt outstanding under the Second Amended Credit Agreement that is solely due to changes in the benchmark interest rate.

On December 19, 2012, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$150 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). On a monthly basis, the interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid. The notional amount of the interest rate swap decreases quarterly until its expiration date, which is currently December 19, 2017.

On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$42.5 million with Wells Fargo to fix the one-month LIBOR rate at 1.12%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). On a monthly basis, the interest rates under both the interest rate swap and the underlying debt reset, the swap is settled with the counterparty, and interest is paid. The notional amount of the interest rate swap increases quarterly by an amount equal to the decrease of the hedge entered into on December 19, 2012, up to the amount of \$175 million. The interest rate swap is scheduled to expire on July 6, 2021.

At September 30, 2016 and December 31, 2015, each of our interest rate swaps qualified as a cash flow hedge. The fair value of our interest rate swaps at September 30, 2016 was a liability of approximately \$982,000, which was partially offset by approximately \$382,000 in deferred taxes. The fair value of our interest rate swap at December 31, 2015 was an asset of approximately \$2,000, which was offset by approximately \$1,000 in deferred taxes.

During the three and nine-month periods ended September 30, 2016 and 2015, respectively, the amounts reclassified from accumulated other comprehensive income to earnings due to hedge effectiveness were included in interest

expense in the accompanying consolidated statements of income and were not material.

Foreign Currency Forward Contracts. We forecast our net exposure to various currencies and enter into foreign currency forward contracts in an effort to mitigate that exposure. As of September 30, 2016, we had entered into the following foreign currency forward contracts (amounts in thousands and in local currencies):

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| Currency              | Symbol | Forward Notional Amount |
|-----------------------|--------|-------------------------|
| Euro                  | EUR    | 250                     |
| British Pound         | GBP    | 767                     |
| Chinese Yuan Renminbi | CNY    | 28,425                  |
| Brazilian Real        | BRL    | 3,900                   |
| Australian Dollar     | AUD    | 3,450                   |
| Hong Kong Dollar      | HKD    | 11,000                  |
| Swiss Franc           | CHF    | 210                     |
| Swedish Krona         | SEK    | 3,500                   |
| Canadian Dollar       | CAD    | 3,150                   |

We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at each month-end, and the fair value of our open positions at September 30, 2016 was not material. The effect on our consolidated statements of income for the three and nine-month periods ended September 30, 2016 and 2015 of all forward contracts was not material.

11. Fair Value Measurements. Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of September 30, 2016 and December 31, 2015, consisted of the following (in thousands):

| Description                 | Fair Value Measurements Using          |                                 |   |   |
|-----------------------------|--|---------------------------------|---|---|
|                             | Total Fair Value at September 30, 2016 | Quoted active markets (Level 1) | Significant observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Interest rate contracts (1) | \$ (982 )                              | \$ —                            | \$ (982 )                               | \$ —                                      |

  

| Description                    | Fair Value Measurements Using         |                                 |   |   |
|--------------------------------|---------------------------------------|---------------------------------|---|---|
|                                | Total Fair Value at December 31, 2015 | Quoted active markets (Level 1) | Significant observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Interest rate contracts (1)    | \$ 2                                  | \$ —                            | \$ 2                                    | \$ —                                      |
| Foreign currency contracts (2) | \$ (278 )                             | \$ —                            | \$ (278 )                               | \$ —                                      |

(1) The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as other long-term obligations or other long-term assets in the Consolidated Balance Sheets.

(2) The fair value of the foreign currency contracts is determined using Level 2 fair value inputs and is recorded as accrued expenses in the Consolidated Balance Sheets.

Certain of our business combinations involve the potential for the payment of future contingent consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. See Note 5 for further information regarding these acquisitions. The contingent consideration liability is re-measured at the estimated fair value at each reporting period with the change in fair value recognized within operating expenses in the accompanying consolidated statements of income. We measure the initial liability and re-measure the liability on a recurring basis using Level 3 inputs as defined under authoritative guidance for fair value measurements. Changes in the fair value of our contingent consideration liability during the three and nine-month periods ended September 30, 2016 and 2015 consisted of the following (in thousands):



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|  | Three Months Ended |         | Nine Months Ended |         |
|--|--------------------|---------|-------------------|---------|
|  | September 30,      |         | September 30,     |         |
|  | 2016               | 2015    | 2016              | 2015    |
| Beginning balance  | 898                | 1,949   | \$1,024           | \$1,886 |
| Contingent consideration liability recorded as the result of acquisitions (see Note 5) | —                  | 270     | —                 | 270     |
| Fair value adjustments recorded to income during the period                            | (193 )             | (58 )   | (136 )            | 185     |
| Contingent payments made   | (16 )              | (14 )   | (199 )            | (194 )  |
| Ending balance   | \$689              | \$2,147 | \$689             | \$2,147 |

The recurring Level 3 measurement of our contingent consideration liability and contingent receivable includes the following significant unobservable inputs at September 30, 2016 and December 31, 2015 (amounts in thousands):

| Contingent consideration liability (asset) | Fair value at September 30, 2016 | Valuation technique  | Unobservable inputs   | Range                           |
|--|----------------------------------|----------------------|---|---------------------------------|
| Revenue-based payments                     | \$ 689                           | Discounted cash flow | Discount rate<br>Probability of milestone payment<br>Projected year of payments | 9.9% - 15%<br>100%<br>2016-2028 |
| Contingent receivable                      | \$ (477 )                        | Discounted cash flow | Discount rate<br>Probability of milestone payment<br>Projected year of payments | 10%<br>51%<br>2016-2019         |
| Contingent consideration liability         | Fair value at December 31, 2015  | Valuation technique  | Unobservable inputs   | Range                           |
| Revenue-based payments                     | \$ 874                           | Discounted cash flow | Discount rate<br>Probability of milestone payment<br>Projected year of payments | 5% - 15%<br>100%<br>2016-2028   |
| Other payments                             | \$ 150                           | Discounted cash flow | Discount rate<br>Probability of milestone payment<br>Projected year of payments | —%<br>100%<br>2016              |

The contingent consideration liability is re-measured to fair value each reporting period using projected revenues, discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans. Increases (decreases) in discount rates and the time to payment may result in lower (higher) fair value measurements. A decrease in the probability of any milestone payment may result in lower fair value measurements. An increase (decrease) in either the discount rate or the time to payment, in isolation, may result in a significantly lower (higher) fair value measurement.



Our determination of the fair value of the contingent consideration liability could change in future periods based upon our ongoing evaluation of these significant unobservable inputs. We intend to record any such change in fair value to operating expenses as part of our cardiovascular segment in our consolidated statements of income. As of September 30, 2016, approximately \$608,000 was included in other long-term obligations and \$81,000 was included in accrued expenses in our consolidated balance sheet. As of December 31, 2015, approximately \$775,000 was included in other long-term obligations and \$249,000 was included in accrued expenses in our consolidated balance sheet. The cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) has been reflected as a cash outflow from financing activities in the accompanying consolidated statements of cash flows.

During the first quarter of 2016, we sold a cost method investment for cash and for the right to receive additional payments based on various contingent milestones. We determined the fair value of the contingent payments using the inputs indicated in the table

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above, and we recorded a contingent receivable asset, which as of September 30, 2016 had a value of approximately \$477,000. We record any changes in fair value to operating expenses as part of our cardiovascular segment in our consolidated statements of income. During the three and nine-month periods ended September 30, 2016, we recorded a loss on the contingent receivable of approximately \$99,000 and \$234,000, respectively. As of September 30, 2016, approximately \$337,000 was included in other long-term assets and approximately \$140,000 was included in other receivables as a current asset in our consolidated balance sheet.

During the three and nine-month periods ended September 30, 2016, we had losses of approximately \$0 and \$90,000, compared to \$85,000 and \$99,000, respectively, for the three and nine-month periods ended September 30, 2015, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition.

The carrying amount of cash and cash equivalents, receivables, and trade payables approximates fair value because of the immediate, short-term maturity of these financial instruments. The carrying amount of long-term debt approximates fair value, as determined by borrowing rates estimated to be available to us for debt with similar terms and conditions. The fair value of assets and liabilities whose carrying value approximates fair value is determined using Level 2 inputs, with the exception of cash and cash equivalents, which are Level 1 inputs.

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12. Goodwill and Intangible Assets. The changes in the carrying amount of goodwill for the nine months ended September 30, 2016 were as follows (in thousands):

|   |           |
|---|-----------|
|   | 2016      |
| Goodwill balance at January 1           | \$184,472 |
| Effect of foreign exchange              | 13        |
| Additions as the result of acquisitions | 28,584    |
| Goodwill balance at September 30        | \$213,069 |

As of September 30, 2016, we had recorded \$8.3 million of accumulated goodwill impairment charges. All of the goodwill balance as of September 30, 2016 and December 31, 2015 related to our cardiovascular segment.

Other intangible assets at September 30, 2016 and December 31, 2015, consisted of the following (in thousands):

|                          | September 30, 2016          |                             |                           |
|--------------------------|-----------------------------|-----------------------------|---------------------------|
|                          | Gross<br>Carrying<br>Amount | Accumulated<br>Amortization | Net<br>Carrying<br>Amount |
| Patents                  | \$13,518                    | \$ (2,952 )                 | \$ 10,566                 |
| Distribution agreements  | 5,626                       | (3,366 )                    | 2,260                     |
| License agreements       | 20,448                      | (3,113 )                    | 17,335                    |
| Trademarks               | 12,369                      | (3,080 )                    | 9,289                     |
| Covenants not to compete | 1,021                       | (912 )                      | 109                       |
| Customer lists           | 21,893                      | (14,751 )                   | 7,142                     |
| Royalty agreements       | 267                         | (267 )                      | —                         |
| <b>Total</b>             | <b>\$75,142</b>             | <b>\$ (28,441 )</b>         | <b>\$ 46,701</b>          |

|                          | December 31, 2015           |                             |                           |
|--------------------------|-----------------------------|-----------------------------|---------------------------|
|                          | Gross<br>Carrying<br>Amount | Accumulated<br>Amortization | Net<br>Carrying<br>Amount |
| Patents                  | \$12,014                    | \$ (2,595 )                 | \$ 9,419                  |
| Distribution agreements  | 5,626                       | (2,853 )                    | 2,773                     |
| License agreements       | 19,109                      | (2,438 )                    | 16,671                    |
| Trademarks               | 7,259                       | (2,554 )                    | 4,705                     |
| Covenants not to compete | 1,028                       | (873 )                      | 155                       |
| Customer lists           | 20,793                      | (15,023 )                   | 5,770                     |
| Royalty agreements       | 267                         | (267 )                      | —                         |
| <b>Total</b>             | <b>\$66,096</b>             | <b>\$ (26,603 )</b>         | <b>\$ 39,493</b>          |

Aggregate amortization expense for the three and nine-month periods ended September 30, 2016 was approximately \$5.7 million and \$13.6 million, respectively, and approximately \$3.7 million and \$11.1 million for the three and nine-month periods ended September 30, 2015, respectively.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of September 30, 2016 (in thousands):

Year Ending December 31

|                |         |
|----------------|---------|
| Remaining 2016 | \$5,558 |
| 2017           | 21,646  |
| 2018           | 21,171  |
| 2019           | 20,854  |
| 2020           | 19,788  |

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13. Commitments and Contingencies. In the ordinary course of business, we are involved in various claims and litigation matters. These claims and litigation matters may include actions involving product liability, intellectual property, contractual, and employment or other matters that are significant to our business. On October 19, 2016, we were informed that the United States Attorney's Office is conducting an investigation that is focused on our marketing and promotion of certain products. We are in the process of responding to the subpoena and intend to cooperate fully with the subpoena. Based upon our review of currently available information, we do not believe that any such actions are likely to be, individually or in the aggregate, materially adverse to our business, financial condition, results of operations or liquidity. However, in the event of unexpected further developments, it is possible that the ultimate resolution of these matters, or other similar matters, if unfavorable, may be materially adverse to our business, financial condition, results of operations or liquidity. Legal costs for these matters, such as outside counsel fees and expenses, are charged to expense in the period incurred.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Disclosure Regarding Forward-Looking Statements

This Report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements in this Report, 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 our management for future operations, any statements concerning proposed new products or services, any statements regarding the acquisition, integration, development or commercialization of the business or assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this Report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. 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 comparable terminology. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Our actual results will likely vary, and may vary materially, from those projected or assumed in the forward-looking statements. Our financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including risks relating to product recalls and product liability claims; potential restrictions on our liquidity or our ability to operate our business within the term of our current credit agreement, and the consequences of any default under that agreement; possible infringement of our technology or the assertion that our technology infringes the rights of other parties; possible injunctions, fines, penalties or other adverse consequences if it is determined that we have violated laws regarding our marketing or promotional practices; the potential imposition of fines, penalties, or other adverse consequences if our employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; expenditures relating to research, development, testing and regulatory approval or clearance of our products and the risk that such products may not be developed successfully or approved for commercial use; greater governmental scrutiny and regulation of the medical device industry; reforms to the 510(k) process administered by the U.S. Food and Drug Administration (the "FDA"); laws targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in, or our failure to comply with, governing regulations; increases in the price of commodity components; negative changes in economic and industry conditions in the United States and other countries; termination or interruption of relationships with our suppliers, or failure of such suppliers to perform; our potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through recent, proposed or future acquisitions; fluctuations in

exchange rates of EUR, CNY, GBP, BRL, MXN, CAD, and other foreign currencies relative to the U.S. Dollar; our need to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations; concentration of our revenues among a few products and procedures; development of new products and technology that could render our existing products obsolete; market acceptance of new products; volatility in the market price of our common stock; modification or limitation of governmental or private insurance reimbursement policies; changes in health care markets related to health care reform initiatives; failures to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; uncertainties associated with potential healthcare policy changes which may have a material adverse effect on our business and results of operations; introduction of products in a timely fashion; price and product competition; availability of labor and materials; cost increases; fluctuations in and obsolescence of inventory; and other factors referred to in Part II, Item 1A "Risk Factors" of this Report, Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, and other materials filed with the Securities and Exchange Commission. All subsequent forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates.

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OVERVIEW

The following discussion and analysis of our financial condition and results of operation should be read in conjunction with the consolidated financial statements and related condensed notes thereto, which are included in Part I of this Report.

We design, develop, manufacture, and market medical products for interventional, diagnostic, and therapeutic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology medical device products which assist in diagnosing and treating coronary artery disease, peripheral vascular disease and other non-vascular diseases and includes embolotherapeutic, cardiac rhythm management ("CRM"), electrophysiology ("EP"), and interventional oncology and spine devices. Our endoscopy segment consists of gastroenterology and pulmonology devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

For the three months ended September 30, 2016, we reported sales of approximately \$157.0 million, up approximately \$20.9 million, or 15.3%, over sales for the three months ended September 30, 2015 of approximately \$136.1 million. For the nine months ended September 30, 2016, we reported sales of approximately \$446.1 million, up approximately \$42.4 million or 10.5%, over sales for the nine months ended September 30, 2015 of approximately \$403.7 million.

Gross profit as a percentage of sales was 43.2% for the three-month period ended September 30, 2016 as compared to 43.5% for the three-month period ended September 30, 2015. Gross profit as a percentage of sales was 43.7% for the nine-month period ended September 30, 2016, as compared to 43.5% for the nine-month period ended September 30, 2015.

Net income for the three months ended September 30, 2016 was approximately \$1.0 million, or \$0.02 per share, as compared to \$4.8 million, or \$0.11 per share, for the quarter ended September 30, 2015. For the nine-month period ended September 30, 2016, net income was approximately \$12.6 million, or \$0.28 per share, as compared to \$17.4 million, or \$0.39 per share, for the nine-month period ended September 30, 2015.

During February 2016, we purchased the HeRO Graft device and other related assets from CryoLife, Inc., a developer of medical devices based in Kennesaw, GA, for \$18.5 million. Sales for the HeRO Graft device were approximately \$1.9 million and \$5.2 million for the three and nine-month periods ended September 30, 2016, respectively.

On July 6, 2016, we acquired DFINE for an initial payment of \$97.5 million to certain stockholders of DFINE and approximately \$578,000 related to a net working capital adjustment, subject to review by Merit and the preferred stockholders of DFINE, in a merger transaction through which DFINE became our wholly-owned subsidiary. Sales related to DFINE for the three-month period ended September 30, 2016 were approximately \$7.0 million.

We continue to focus our efforts on expanding our presence in foreign markets, particularly Europe, Middle East and Africa, China, Southeast Asia, Japan, Brazil, Australia and Canada, in an effort to expand our market opportunities. These efforts have increased our selling, general and administrative expenses in the short term, but we believe over time they will help us improve our profitability.

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## RESULTS OF OPERATIONS

The following table sets forth certain operational data as a percentage of sales for the three and nine-month periods ended September 30, 2016 and 2015, as indicated:

|  | Three<br>Months<br>Ended<br>September<br>30,<br>2016 |       | Nine<br>Months<br>Ended<br>September<br>30,<br>2015 |       |
|--|--|-------|---|-------|
| Net sales                                    | 100%   | 100%  | 100%  | 100%  |
| Gross profit                                 | 43.2   | 43.5  | 43.7  | 43.5  |
| Selling, general and administrative expenses | 33.9   | 28.8  | 31.1  | 28.6  |
| Research and development expenses            | 7.3  | 7.7   | 7.5   | 7.3   |
| Contingent consideration expense (benefit)   | (0.1)  | —     | —   | 0.1   |
| Acquired in-process research and development | 0.2  | 0.7   | 0.1   | 0.2   |
| Income from operations                       | 1.9  | 6.3   | 5.0   | 7.3   |
| Other (expense) - net                        | (1.9)  | (1.4) | (1.5)   | (1.2) |
| Income before income taxes                   | —  | 4.9   | 3.5   | 6.1   |
| Net income                                   | 0.6  | 3.5   | 2.8   | 4.3   |

Sales. Sales for the three months ended September 30, 2016 increased by 15.3%, or approximately \$20.9 million, compared to the corresponding period of 2015. Sales for the nine months ended September 30, 2016 increased by 10.5%, or approximately \$42.4 million, compared to the corresponding period of 2015. Listed below are the sales by product category within each of our business segments for the three and nine-month periods ended September 30, 2016 and 2015 (in thousands):

|                                 |          | Three Months<br>Ended September<br>30, |           |          | Nine Months Ended<br>September 30, |           |
|---------------------------------|----------|--|-----------|----------|------------------------------------|-----------|
|                                 | % Change | 2016                                   | 2015      | % Change | 2016                               | 2015      |
| <b>Cardiovascular</b>           |          |  |           |          |                                    |           |
| Stand-alone devices             | 35.0%    | \$51,901                               | \$38,451  | 23.0%    | \$141,627                          | \$115,125 |
| Custom kits and procedure trays | 0.8%     | 30,230                                 | 29,986    | 1.6%     | 89,174                             | 87,738    |
| Inflation devices               | 2.6%     | 18,364                                 | 17,894    | (0.9)%   | 54,768                             | 55,284    |
| Catheters                       | 20.1%    | 29,529                                 | 24,587    | 14.0%    | 82,274                             | 72,183    |
| Embolization devices            | (1.1)%   | 11,207                                 | 11,328    | 1.8%     | 33,937                             | 33,323    |
| CRM/EP                          | 7.5%     | 9,368                                  | 8,711     | 8.2%     | 26,888                             | 24,854    |
| Total                           | 15.0%    | 150,599                                | 130,957   | 10.3%    | 428,668                            | 388,507   |
| <b>Endoscopy</b>                |          |  |           |          |                                    |           |
| Endoscopy devices               | 24.3%    | 6,376                                  | 5,129     | 14.5%    | 17,455                             | 15,238    |
| Total                           | 15.3%    | \$156,975                              | \$136,086 | 10.5%    | \$446,123                          | \$403,745 |

Our cardiovascular sales increased approximately \$19.6 million, or 15.0%, for the three months ended September 30, 2016, on sales of approximately \$150.6 million, compared to sales of \$131.0 million for the corresponding period of 2015. Our cardiovascular sales increased approximately \$40.2 million, or 10.3%, for the nine months ended September 30, 2016, on sales of approximately \$428.7 million, compared to sales of \$388.5 million for the



corresponding period of 2015. This improvement was largely the result of increased sales of our stand-alone devices (particularly our diagnostic guide wire product line, tubing product line and hydrophilic guide wire product line) and our catheters. In July, we acquired DFINE, which contributed to higher sales for the three months ended September 30, 2016. The introduction of the HeRO Graft product in the first quarter of 2016 also contributed to the increase in sales in the cardiovascular segment for the periods presented. The decrease in sales of inflation devices for the nine-month period ended September 30, 2016 was primarily due to reduced sales to a large OEM customer and two large distributors.

Our endoscopy sales increased approximately \$1.2 million, or 24.3% for the three months ended September 30, 2016, on sales of approximately \$6.4 million, when compared to sales for the corresponding period of 2015 of approximately \$5.1 million. Our endoscopy sales increased approximately \$2.2 million, or 14.5%, for the nine months ended September 30, 2016, on sales of approximately \$17.5 million, when compared to sales for the corresponding period of 2015 of approximately \$15.2 million. This

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increase was primarily related to an increase in sales of our EndoMAXX™ fully covered esophageal stent, as well as related to the introduction of our Elation® Balloon Dilator.

**Gross Profit.** Gross profit as a percentage of sales decreased to 43.2% for the three months ended September 30, 2016, compared to 43.5% for the corresponding period of 2015. The decrease in gross margin for the three-month period ended September 30, 2016 compared to the corresponding period in 2015 was primarily related to the increased amortization of intangibles related to the DFINE acquisition, which was offset by our increased focus on higher margin products. Gross profit as a percentage of sales increased to 43.7% for the nine months ended September 30, 2016, compared to 43.5% for the nine months ended September 30, 2015. The increase in gross margin for the nine month period ended September 30, 2016 compared to the corresponding period in 2015 was primarily related to our increased focus on higher margin products and the suspension of the medical device tax in the United States, which was offset by increased amortization as part of the DFINE acquisition.

**Operating Expenses.** Selling, general and administrative ("SG&A") expenses increased approximately \$14.0 million, or 35.7%, for the three months ended September 30, 2016, compared to the three months ended September 30, 2015. As a percentage of sales, SG&A expenses increased to 33.9% of sales for the three months ended September 30, 2016, compared to 28.8% of sales for the three months ended September 30, 2015. For the nine months ended September 30, 2016, SG&A expenses as a percentage of sales increased to 31.1%, compared to 28.6% for the nine months ended September 30, 2015. The increase in SG&A expense in both periods was primarily related to increased acquisition costs, severance expenses and foreign market expansion costs, which were partially offset by decreases of approximately \$332,000 for the three months ended September 30, 2016 and approximately \$1.1 million for the nine months ended September 30, 2016 in our foreign currency-denominated SG&A expense, which in turn was due primarily to the strengthening of the U.S. Dollar against the Euro during the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015.

**Research and Development Expenses.** Research and development ("R&D") expenses were 7.3% of sales for the three months ended September 30, 2016, compared to 7.7% of sales for the three months ended September 30, 2015. The decrease in R&D expenses as a percentage of sales for the three months ended September 30, 2016 was largely due to an increased focus on managing our R&D expenditures. Research and development expenses were 7.5% of sales for the nine months ended September 30, 2016, compared to 7.3% of sales for the nine months ended September 30, 2015. The increase in R&D expenses as a percentage of sales for the nine months ended September 30, 2016 was largely due to hiring of additional research and development personnel to support various new product developments.

**Operating Income.** The following table sets forth our operating income by business segment for the three and nine-month periods ended September 30, 2016 and 2015 (in thousands):

|                        | Three<br>Months<br>Ended<br>September<br>30,<br>2016 |       | Nine Months<br>Ended<br>September 30,<br>2015 |        |
|------------------------|--|-------|---|--------|
| Operating Income       |  |       |   |        |
| Cardiovascular         | 1,954  | 7,995 | 19,482  | 27,323 |
| Endoscopy              | 1,033  | 552   | 2,792   | 2,170  |
| Total operating income | 2,987  | 8,547 | 22,274  | 29,493 |

**Cardiovascular Operating Income.** During the three months ended September 30, 2016, we reported income from operations of approximately \$2.0 million from our cardiovascular business segment, compared to income from

operations from this segment of approximately \$8.0 million for the corresponding period of 2015. The decrease in operating income in our cardiovascular segment was primarily the result of increased SG&A expenses relating to acquisition and severance costs from the DFINE acquisition and increased R&D expenses, which were partially offset by a decrease of approximately \$332,000 for the three months ended September 30, 2016 in our foreign currency-denominated SG&A expense, which in turn was due primarily to the strengthening of the U.S. Dollar against the Euro during the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

During the nine months ended September 30, 2016, we reported income from operations of approximately \$19.5 million from our cardiovascular business segment, compared to income from operations from this segment of approximately \$27.3 million for the corresponding period of 2015. The decrease in operating income in our cardiovascular segment was primarily the result of increased SG&A expenses relating to acquisition and severance costs from the DFINE acquisition and increased R&D expenses, which were partially offset by a decrease of approximately \$1.1 million for the nine months ended September 30, 2016 in our foreign currency-denominated SG&A expense, which, in turn, was due primarily to the strengthening of the U.S. Dollar against the Euro during the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015.

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Endoscopy Operating Income. During the three months ended September 30, 2016, we reported income from operations of approximately \$1.0 million from our endoscopy business segment, compared to income from operations from this segment of approximately \$552,000 for the corresponding period of 2015. The increase in operating income in our endoscopy segment was primarily the result of higher sales and gross profits, as well as lower SG&A expenses as a percentage of sales.

During the nine months ended September 30, 2016, we reported income from operations of approximately \$2.8 million from our endoscopy business segment, compared to income from operations from this segment of approximately \$2.2 million for the corresponding period of 2015. The increase in operating income in our endoscopy segment was primarily the result of higher sales and gross profits, as well as lower SG&A expenses as a percentage of sales.

Other Expense - Net. Other expense, net, for the three months ended September 30, 2016 was approximately \$3.0 million, compared to other expense, net, of approximately \$1.9 million for the corresponding period of 2015. Other expense, net, for the nine months ended September 30, 2016 was approximately \$6.5 million, compared to other expense, net, of approximately \$4.8 million for the corresponding period of 2015. The increase in other expense was principally the result of increased interest expense related to higher debt balances as a result of our acquisition of DFINE, as well as losses on changes in foreign exchange rates.

Income Taxes. Our provision for income taxes for the three months ended September 30, 2016 was a tax benefit of approximately \$978,000, compared to a tax expense of approximately \$1.8 million for the corresponding period of 2015. The income tax benefit recorded during the third quarter of 2016 was primarily due to a decrease in the estimated annual effective tax rate and certain discrete tax benefits recorded during the period. The decrease in the estimated annual effective tax rate was due to shifts in the projected mix of earnings by jurisdiction during the three-month period ended September 30, 2016. The discrete tax benefits recorded during the third quarter were primarily related to the release of certain liabilities related to unrecognized tax benefits due to statute of limitation expirations and favorable adjustments to the research and development tax credit.

Our provision for income taxes for the nine months ended September 30, 2016 and 2015 was a tax expense of approximately \$3.1 million and a tax expense of approximately \$7.3 million, respectively, which resulted in an effective tax rate of 20.0% and 29.4%, respectively. The decrease in the effective income tax rate for the nine-month period ended September 30, 2016, when compared to the corresponding period of 2015, was primarily related to shifts in our projected mix of earnings by jurisdiction during the three-month period ended September 30, 2016.

Net Income. During the three months ended September 30, 2016, we reported net income of \$1.0 million, a decrease of approximately 79.8% from \$4.8 million for the corresponding period of 2015. The decrease in net income was primarily due to acquisition and severance costs, as well as increased interest expense as a result of higher debt balances related to the DFINE acquisition, and decreased gross margin as a percentage of sales, which were partially offset by a lower effective tax rate.

During the nine months ended September 30, 2016, we reported net income of \$12.6 million, a decrease of approximately 27.5% from \$17.4 million for the corresponding period of 2015. The decrease in net income was primarily due to acquisition and severance costs, as well as increased interest expense related to higher debt balances related to the DFINE acquisition, and higher research and development costs as a percentage of sales, which were partially offset by higher gross margin as a percentage of sales and a lower effective tax rate.

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LIQUIDITY AND CAPITAL RESOURCES

Capital Commitments and Contractual Obligations

At September 30, 2016 and December 31, 2015, we had cash and cash equivalents of approximately \$17.3 million and \$4.2 million respectively, of which \$16.1 million and \$3.7 million, respectively, were held by foreign subsidiaries. For each of our foreign subsidiaries, we make an evaluation as to whether the earnings are intended to be repatriated to the United States or held by the foreign subsidiary for permanent reinvestment. The cash held by our foreign subsidiaries for permanent reinvestment is used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations. A deferred tax liability has been accrued for the earnings that are available to be repatriated to the United States.

In addition, cash held by our subsidiary in China is subject to local laws and regulations that require government approval for the transfer of such funds to entities located outside of China. As of September 30, 2016 and December 31, 2015, we had cash and cash equivalents of approximately \$6.4 million and \$1.7 million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. Cash provided by operating activities during the nine months ended September 30, 2016 and September 30, 2015 was primarily the result of net income excluding non-cash items offset by shifts in working capital.

Our working capital as of September 30, 2016 and December 31, 2015 was approximately \$147.8 million and \$116.1 million, respectively. The increase in working capital as of September 30, 2016 compared to December 31, 2015 was primarily the result of increases in cash, trade receivables, and inventories, as well as a decrease in trade payables, which were partially offset by an increase in accrued expenses and a decrease in other receivables. As of September 30, 2016, we had a current ratio of 2.71 to 1.

During the nine months ended September 30, 2016, our inventory balance increased approximately \$10.9 million from approximately \$106.0 million at December 31, 2015 to approximately \$116.9 million at September 30, 2016. The increase in the inventory balance was due to several factors, including our acquisitions of DFINE and of the HeRO Graft device and increases in raw materials and work-in-process, as well as the launch of our direct sales activities in Canada, and was partially offset by a decrease in our finished goods inventory as a result of increased sales. The trailing twelve months inventory turns as of September 30, 2016 decreased to 3.00, compared to 3.11 as of September 30, 2015.

Cash flows provided by (used in) financing activities. Cash provided by financing activities for the nine-month period ended September 30, 2016 was approximately \$123.5 million, compared to cash used in financing activities of approximately \$7.5 million for the nine-month period ended September 30, 2015, a change of approximately \$131.0 million. This change was primarily the result of increased debt financing related to acquisitions, principally our acquisitions of DFINE and the HeRO Graft device and other related assets, as well as reduced proceeds from the issuance of common stock, during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015.

The terms of the Second Amended Credit Agreement provide for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$275 million, which includes a reserve of \$25 million to make swingline loans from time to time. The term loan is payable in quarterly installments in the amounts provided in the Second Amended Credit Agreement until the maturity date of July 6, 2021, at which time the term and revolving credit loans, together with accrued interest thereon, will be due and payable. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans, term loans, and all swingline loans in whole or in part, subject to certain minimum thresholds, without premium or penalty, other than breakage costs.

Revolving credit loans denominated in dollars and term loans made under the Second Amended Credit Agreement bear interest, at our election, at either a Base Rate or Eurocurrency Base Rate (as such terms are defined in the Second Amended Credit Agreement) plus the applicable margin, which increases as our Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) increases. Revolving credit loans denominated in an Alternative Currency (as defined in the Second Amended Credit Agreement) shall bear interest at the Eurocurrency rate plus the applicable margin. Swingline loans bear interest at the base rate plus the applicable margin. Upon an event of default, the interest rate may be increased by 2.0%. The revolving credit commitment will also carry a commitment fee of 0.15% to 0.4% per annum on the unused portion.

The Second Amended Credit Agreement is collateralized by substantially all of our assets. The Second Amended Credit Agreement contains covenants, representations and warranties, and other terms customary for loans of this nature. The Second Amended Credit Agreement requires that we maintain certain financial covenants, as follows:

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|  | Covenant Requirement |
|--|----------------------|
| Consolidated Total Leverage Ratio (1)  |                      |
| Through March 31, 2017                 | 4.5 to 1.0           |
| April 1, 2017 through June 30, 2017    | 4.0 to 1.0           |
| July 1, 2017 through December 31, 2017 | 3.75 to 1.0          |
| January 1, 2018 through March 31, 2018 | 3.5 to 1.0           |
| April 1, 2018 and thereafter           | 3.25 to 1.0          |
| Consolidated EBITDA (2)                | 1.25 to 1.0          |
| Consolidated Net Income (3)            | \$0                  |
| Facility Capital Expenditures (4)      | \$30 million         |

(1) Maximum Consolidated Total Leverage Ratio (as defined in the Second Amended Credit Agreement) as of any fiscal quarter end.

Minimum ratio of Consolidated EBITDA (as defined in the Second Amended Credit Agreement and adjusted for certain (2) expenditures) to Consolidated Fixed Charges (as defined in the Second Amended Credit Agreement) for any period of four consecutive fiscal quarters.

Minimum level of Consolidated Net Income (as defined in the (3) Second Amended Credit Agreement) for certain periods, and subject to certain adjustments.

Maximum level of the aggregate amount of all Facility Capital (4) Expenditures (as defined in the Second Amended Credit Agreement) in any fiscal year.

Additionally, the Second Amended Credit Agreement contains customary events of default and affirmative and negative covenants for transactions of this type. As of September 30, 2016, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of September 30, 2016, we had outstanding borrowings of approximately \$328.4 million under the Second Amended Credit Agreement, with available borrowings of approximately \$91.6 million, based on the leverage ratio in the terms of the Second Amended Credit Agreement. Our interest rate as of September 30, 2016 was a fixed rate of 3.48% on \$131.3 million and 3.62% on \$43.8 million as a result of interest rate swaps (see Note 10), a variable floating rate of 3.02% on \$153.0 million and a variable floating rate of 5.00% on approximately \$0.4 million. Our interest rate as of December 31, 2015 was a fixed rate of 2.48% on \$135.0 million as a result of an interest rate swap, a variable floating rate of 1.74% on \$65.8 million, and a variable floating rate of 2.12% on approximately \$6.8 million.

Cash flows used in investing activities. Cash used in investing activities was approximately \$146.8 million for the nine months ended September 30, 2016, compared to approximately \$50.7 million for the nine months ended September 30, 2015, an increase of approximately \$96.1 million. This increase was primarily a result of more cash paid for acquisitions during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015, principally the cash paid in the acquisitions of DFINE and the HeRO Graft device (see Note 5 of the condensed notes to our consolidated financial statements). Capital expenditures for property and equipment were approximately \$26.5 million and \$39.5 million, respectively, for the nine-month periods ended September 30, 2016 and 2015, a decrease of approximately \$13.0 million.

We currently believe that our existing cash balances, anticipated future cash flows from operations, equipment financing and borrowings under the Second Amended Credit Agreement, as amended and restated, will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The SEC has requested that all registrants address their most critical accounting policies. The SEC has indicated that a “critical accounting policy” is one which is both important to the representation of the registrant’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We base our estimates on past experience and on various other assumptions our management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results will differ, and may differ materially from these estimates under different assumptions or conditions. Additionally, changes in accounting estimates could occur in the future from period to period. Our management has discussed the development and selection of our most critical financial estimates with the audit committee of our Board of Directors. The following paragraphs identify our most critical accounting policies:

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**Inventory Obsolescence.** Our management reviews on a quarterly basis inventory quantities on hand for unmarketable and/or slow-moving products that may expire prior to being sold. This review includes quantities on hand for both raw materials and finished goods. Based on this review, we provide adjustments for any slow-moving finished good products or raw materials that we believe will expire prior to being sold or used to produce a finished good and any products that are unmarketable. This review of inventory quantities for unmarketable and/or slow moving products is based on forecasted product demand prior to expiration lives.

Forecasted unit demand is derived from our historical experience of product sales and production raw material usage. If market conditions become less favorable than those projected by our management, additional inventory write-downs may be required. During the years ended December 31, 2015, 2014 and 2013, we recorded obsolescence expense of approximately \$2.8 million, \$2.3 million, and \$2.7 million, respectively, and wrote off approximately \$2.5 million, \$2.4 million, and \$2.8 million, respectively. Based on this historical trend, we believe that our inventory balances as of September 30, 2016 have been accurately adjusted for any unmarketable and/or slow moving products that may expire prior to being sold.

**Allowance for Doubtful Accounts.** A majority of our receivables are with hospitals which, over our history, have demonstrated favorable collection rates. Therefore, we have experienced relatively minimal bad debts from hospital customers. In limited circumstances, we have written off bad debts as the result of the termination of our business relationships with foreign distributors. The most significant write-offs over our history have come from U.S. custom procedure tray manufacturers who bundle our products in surgical trays.

We maintain allowances for doubtful accounts relating to estimated losses resulting from the inability of our customers to make required payments. These allowances are based upon historical experience and a review of individual customer balances. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

**Stock-Based Compensation.** We measure stock-based compensation cost at the grant date based on the value of the award and recognize the cost as an expense over the term of the vesting period. Judgment is required in estimating the fair value of share-based awards granted and their expected forfeiture rate. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

**Income Taxes.** Under our accounting policies, we initially recognize a tax position in our financial statements when it becomes more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax positions that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authorities assuming full knowledge of the position and all relevant facts. Although we believe our provisions for unrecognized tax positions are reasonable, we can make no assurance that the final tax outcome of these matters will not be different from that which we have reflected in our income tax provisions and accruals. The tax law is subject to varied interpretations, and we have taken positions related to certain matters where the law is subject to interpretation. Such differences could have a material impact on our income tax provisions and operating results in the period(s) in which we make such determination.

**Goodwill and Intangible Asset Impairment and Contingent Consideration.** We test our goodwill balances for impairment as of July 1 of each year, or whenever impairment indicators arise. We utilize several reporting units in evaluating goodwill for impairment. We assess the estimated fair value of reporting units using a combination of a market-based approach with a guideline public company method and a discounted cash flow method. If the carrying amount of a reporting unit exceeds the fair value of the reporting unit, an impairment charge is recognized in an amount equal to the excess of the carrying amount of the reporting unit goodwill over implied fair value of that goodwill. This analysis requires significant judgment, including estimation of future cash flows and the length of time

they will occur, which is based on internal forecasts, and a determination of a discount rate based on our weighted average cost of capital. During our annual test of goodwill balances in 2016, which was completed during the third quarter of 2016, we determined that the fair value of each reporting unit with goodwill exceeded the carrying amount by a significant amount.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable. This analysis requires similar significant judgments as those discussed above regarding goodwill, except that undiscounted cash flows are compared to the carrying amount of intangible assets to determine if impairment exists. All of our intangible assets are subject to amortization.

Contingent consideration is an obligation by the buyer to transfer additional assets or equity interests to the former owner upon reaching certain performance targets. Certain of our business combinations involve the potential for the payment of future contingent

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consideration, generally based on a percentage of future product sales or upon attaining specified future revenue milestones. In connection with a business combination, any contingent consideration is recorded on the acquisition date based upon the consideration expected to be transferred in the future. We utilize a discounted cash flow method, which includes a probability factor for milestone payments, in valuing the contingent consideration liability. We re-measure the estimated liability each quarter and record changes in the estimated fair value through operating expense in our consolidated statements of income. Significant increases or decreases in our estimates could result in changes to the estimated fair value of our contingent consideration liability, as the result of changes in the timing and amount of revenue estimates, as well as changes in the discount rate or periods.

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## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

**Currency Risk.** Our principal market risk relates to changes in the value of the Euro (EUR), Chinese Yuan Renminbi (CNY), and British Pound (GBP) relative to the value of the U.S. Dollar (USD). We also have a limited market risk relating to the Hong Kong Dollar (HKD), Mexican Peso (MXN), Australian Dollar (AUD), Canadian Dollar (CAD), Brazilian Real (BRL), Swedish Krona (SEK), and Danish Krone (DKK). Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the three-month period ended September 30, 2016, a portion of our revenues (approximately \$39.6 million, representing approximately 26% of our aggregate revenues), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Our Euro-denominated revenue represents our largest single currency risk. However, our Euro-denominated expenses associated with our European operations (manufacturing sites, a distribution facility and sales representatives) provide a natural hedge. Accordingly, changes in the Euro, and in particular a strengthening of the U.S. Dollar against the Euro, will positively affect our net income. A strengthening U.S. dollar against the Euro of 10% would increase net income by approximately \$2.5 million dollars on an annual basis. Conversely, a weakening U.S. dollar against the Euro of 10% would decrease net income by approximately \$2.5 million dollars on an annual basis. A strengthening U.S. dollar against the CNY of 10% would decrease net income by approximately \$4.0 million dollars on an annual basis. Conversely, a weakening U.S. dollar against the CNY of 10% would increase net income by approximately \$4.0 million dollars on an annual basis. During the three-month period ended September 30, 2016, exchange rate fluctuations of foreign currencies against the U.S. Dollar resulted in a decrease in our gross revenues of approximately \$1.1 million, or 0.7%, and a decrease of 1.2% in gross profit, primarily as a result of unfavorable impacts to revenue due to sales denominated in CNY and GBP, partially offset by favorable impacts due to increases in Mexican manufacturing costs denominated in MXN.

We forecast our net exposure to various currencies and enter into foreign currency forward contracts to mitigate that exposure. As of September 30, 2016, we had entered into the following foreign currency forward contracts (amounts in thousands and in local currencies):

| Currency              | Symbol | Forward Notional Amount |
|-----------------------|--------|-------------------------|
| Euro                  | EUR    | 250                     |
| British Pound         | GBP    | 767                     |
| Chinese Yuan Renminbi | CNY    | 28,425                  |
| Brazilian Real        | BRL    | 3,900                   |
| Australian Dollar     | AUD    | 3,450                   |
| Hong Kong Dollar      | HKD    | 11,000                  |
| Swiss Franc           | CHF    | 210                     |
| Swedish Krona         | SEK    | 3,500                   |
| Canadian Dollar       | CAD    | 3,150                   |

We enter into similar transactions at various times during the year to partially offset exchange rate risks we bear throughout the year. These contracts are marked to market at each month-end.

The effect on our consolidated statements of income for the three and nine-month periods ended September 30, 2016 and September 30, 2015 of all forward contracts, and the fair value of our open positions at September 30, 2016, were not material.

**Interest Rate Risk.** As discussed in Note 9 to our consolidated financial statements, as of September 30, 2016, we had outstanding borrowings of approximately \$328.4 million under the Second Amended Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. As part of our efforts to mitigate interest rate risk, on December 19, 2012, we entered into a LIBOR-based interest rate swap agreement having an initial notional amount of \$150.0 million with Wells Fargo to fix the one-month LIBOR rate at 0.98%. As of September 30, 2016, a notional amount of \$131.3 million remained on the interest rate swap agreement, which expires on December

19, 2017. On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap having an initial notional amount of \$42.5 million with Wells Fargo to fix the one-month LIBOR rate at 1.12%. The notional amount of this interest rate swap increases quarterly by an amount equal to the decrease of the hedge entered into on December 19, 2012, up to the amount of \$175 million. The interest rate swap is scheduled to expire on July 6, 2021. These instruments are intended to reduce our exposure to interest rate fluctuations and were not entered into for speculative purposes. Excluding the amount that is subject to a fixed rate under the interest rate swap and assuming the current level of borrowings remained the same, it is estimated that our interest expense and income before income taxes would change by approximately \$1.5 million annually for each one percentage point change in the average interest rate under these borrowings.

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In the event of an adverse change in interest rates, our management would likely take actions to mitigate our exposure. However, due to the uncertainty of the actions that would be taken and their possible effects, additional analysis is not possible at this time. Further, such analysis would not consider the effects of the change in the level of overall economic activity that could exist in such an environment.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2016. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Except as set forth below, during the quarter ended September 30, 2016, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934).

On July 6, 2016, we completed our acquisition of DFINE. We are currently integrating the policies, processes, employees, technology and operations of DFINE. Management will continue to evaluate our internal control over financial reporting as we execute acquisition integration activities.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 13 "Commitments and Contingencies" set forth in the notes to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

ITEM 1A. RISK FACTORS

In addition to other information set forth in this Report, readers should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015 (the "Form 10-K"), which could materially affect our business, financial condition or future results. The risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results.

The risk factors identified in Part I, Item 1A of the Form 10-K are supplemented by the following additional risk factors:

We may be unable to manage rapid increases in the demand for our products, particularly if the increase may not be sustained.

Due to regulatory issues experienced by a competitor, we have recently experienced an increase in demand for certain of our products. We do not know whether this increase will be short-term, medium-term or sustained, nor can we presently estimate the amount of the increase. As a result of this increase, demand for those products may exceed our inventory and manufacturing capacity. In response to the development, we have increased capacity at some of our existing facilities; however, this increase may not be sufficient to meet demand and could place stress on our human and other resources. It may also place stress on our relationships with third-party suppliers. In the short term, we cannot outsource this manufacturing because our products need to be manufactured to exact specifications, in a clean environment and by a manufacturer that satisfies certain regulatory requirements. This is forcing us to make allocation decisions among existing and new customers. We may be unable to efficiently manage this increase in demand for certain products. Failure to efficiently manage the situation could result in the loss of skilled employees or damage our existing supply relationships. A rapid increase in production may also lead to failures in our internal controls, including those related to quality, operations or financial reporting. Any such failures on our part may result in long-term declines in our profitability and results of operations.

The agreements and instruments governing our long-term debt contain restrictions, limitations and default remedies that could significantly affect our ability to operate our business, our liquidity and our ability to continue as a going concern.

We entered into the Second Amended Credit Agreement with certain lenders and Wells Fargo Bank, National Association as administrative agent, in connection with our acquisition by merger of DFINE. The Second Amended Credit Agreement contains a number of significant covenants that could limit or restrict our ability to operate our business, our liquidity or our results of operations. These covenants restrict, among other things, our incurrence of indebtedness, creation of liens or pledges on our assets, mergers or similar combinations or liquidations, asset dispositions, repurchases or redemptions of equity interests or debt, issuances of equity, payment of dividends and certain distributions, and entry into related party transactions.



We have pledged substantially all of our assets as collateral for the Second Amended Credit Agreement. Our breach of any covenant in the Second Amended Credit Agreement, not otherwise cured, waived or amended, could result in a default under the Second Amended Credit Agreement and could trigger acceleration of underlying obligations. The administrative agent and lenders under the Second Amended Credit Agreement have available to them the remedies typically available to lenders and secured parties, including the ability to foreclose on the collateral we have pledged. Any default under the Second Amended Credit Agreement would at a minimum harm ability to service our debt and to fund our prospective capital expenditures and ongoing operations. It could lead to an acceleration of indebtedness and foreclosure on our assets.

The Second Amended Credit Agreement provides for a total potential borrowing base of \$425.0 million, which is \$100.0 million more than the aggregate amount we were permitted to borrow under our prior credit agreement. As a result of this increase in indebtedness, it may be more difficult for us to comply with leverage ratios and other restrictive covenants. We may also have less cash available for operations and investments in our business, as we will be required to use additional cash to satisfy the minimum payment obligations associated with this increased indebtedness.

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The integration of the DFINE business into our existing business will present significant challenges, which may harm our operations.

We may be unable to realize anticipated benefits, and may experience losses, in connection with our acquisition of DFINE. Prior to the acquisition, DFINE was not profitable or cash flow positive. In an effort to make the DFINE operations accretive to our results of operations, we plan to reduce the number of employees at DFINE, have our existing employees assume certain sales and other functions and consolidate a significant portion of the manufacturing activities related to the DFINE products, all without losing important supplier or customer relationships or experiencing a reduction in product quality. We also need to retain and integrate certain key employees and suppliers that are important for the continuation and success of the DFINE business. Although we anticipate delays, the loss of certain employees, suppliers or customers, culture clashes, unbudgeted costs and other issues at certain levels, we may experience any or all of such problems at levels that are more severe or more prolonged than anticipated. In addition, we may experience problems that can be associated with any acquisition in our industry, such as regulatory, infringement, product liability, discrimination or other legal claims or issues. If any such problems or issues arise, we may lose all or part of our investment in DFINE or fail to realize anticipated benefits.

If the FDA or another governmental agency determines that we have violated laws or regulations regarding our marketing or promotional practices, we may be subject to various penalties, including civil or criminal penalties. We have received an administrative subpoena from the U.S. Department of Justice, or DOJ, regarding an investigation which we believe is focused on our marketing and promotion of certain of our products.

The FDA, the DOJ and other regulatory or enforcement agencies actively enforce regulations regarding the marketing and promotion of medical products. If such an agency determines that our marketing or promotional materials or practices violate applicable laws or regulations, it could request that we modify our training or promotional materials or subject us or our officers, directors or employees to various enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. On October 19, 2016, we were informed that the United States Attorney's Office is conducting an investigation that is focused on our marketing and promotion of certain products. We are in the process of responding to the subpoena and intend to cooperate fully with the subpoena. We may not be able to resolve these matters, or any similar matters that may come up in the future, without our company or individuals in our company incurring significant fines, penalties or other significant adverse consequences. Even if we are successful in resolving this matter without incurring significant adverse consequences, responding to the subpoena has resulted and in the future will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations.

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ITEM 6. EXHIBITS

Exhibit No. Description

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following financial information from the quarterly report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements

SIGNATURES

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

MERIT MEDICAL SYSTEMS, INC.

REGISTRANT

Date: November 9, 2016 /s/ FRED P. LAMPROPOULOS  
FRED P. LAMPROPOULOS  
PRESIDENT AND CHIEF EXECUTIVE OFFICER

Date: November 9, 2016 /s/ BERNARD J. BIRKETT  
BERNARD J. BIRKETT  
CHIEF FINANCIAL OFFICER