

MERIT MEDICAL SYSTEMS INC

Form 10-Q

November 08, 2011

Table of Contents

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, 2011.

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

(State or other jurisdiction of incorporation or organization)

87-0447695

(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

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-Q

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

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

Common Stock

41,918,109

Title or class

Number of Shares

Outstanding at November 4, 2011

Table of Contents

MERIT MEDICAL SYSTEMS, INC.
INDEX TO FORM 10-Q

	PAGE
<u>PART I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010</u>	<u>1</u>
<u>Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010</u>	<u>3</u>
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010</u>	<u>4</u>
<u>Condensed Notes to Consolidated Financial Statements</u>	<u>6</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>5</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>21</u>
<u>Item 4. Controls and Procedures</u>	<u>21</u>
<u>PART II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>22</u>
<u>Item 1A. Risk Factors</u>	<u>22</u>
<u>Item 6. Exhibits</u>	<u>22</u>
<u>SIGNATURES</u>	<u>23</u>

Table of Contents

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 CONSOLIDATED BALANCE SHEETS
 SEPTEMBER 30, 2011 AND DECEMBER 31, 2010
 (In thousands)

	September 30, 2011 (unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$5,819	\$3,735
Trade receivables - net of allowances of \$473 and \$593, respectively	40,579	37,362
Employee receivables	199	110
Other receivables	1,442	1,242
Inventories	66,557	60,597
Prepaid expenses and other assets	4,302	2,541
Deferred income tax assets	4,591	4,647
Income tax refunds receivable	467	2,067
Total current assets	123,956	112,301
PROPERTY AND EQUIPMENT:		
Land and land improvements	15,752	12,586
Building	51,072	50,274
Manufacturing equipment	101,660	92,839
Furniture and fixtures	21,302	18,313
Leasehold improvements	12,632	12,121
Construction-in-progress	41,517	13,775
Total	243,935	199,908
Less accumulated depreciation	(81,412)	(71,853)
Property and equipment—net	162,523	128,055
OTHER ASSETS:		
Intangibles - net of accumulated amortization of \$13,498 and \$8,996, respectively	58,544	57,184
Goodwill	61,144	58,675
Deferred income tax assets	4,613	4,140
Other assets	8,053	9,125
Total other assets	132,354	129,124
TOTAL ASSETS	\$418,833	\$369,480
See condensed notes to consolidated financial statements.		(Continued)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2011 AND DECEMBER 31, 2010
(In thousands)

	September 30, 2011 (unaudited)	December 31, 2010
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$23,129	\$20,092
Accrued expenses	21,404	18,890
Advances from employees	798	307
Income taxes payable	2,967	887
Total current liabilities	48,298	40,176
LONG-TERM DEBT	5,619	81,538
DEFERRED INCOME TAX LIABILITIES	1,449	1,267
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	2,417	3,527
DEFERRED COMPENSATION PAYABLE	4,382	4,258
DEFERRED CREDITS	1,682	1,763
OTHER LONG-TERM OBLIGATIONS	4,270	1,336
Total liabilities	68,117	133,865
STOCKHOLDERS' EQUITY:		
Preferred stock—5,000 shares authorized as of September 30, 2011 and December 31, 2010; no shares issued		
Common stock—no par value; 100,000 shares authorized; 41,918 and 35,496 shares issued at September 30, 2011 and December 31, 2010, respectively	165,011	67,091
Retained earnings	185,738	167,664
Accumulated other comprehensive income (loss)	(33) 860
Total stockholders' equity	350,716	235,615
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$418,833	\$369,480
See condensed notes to consolidated financial statements.		(Concluded)

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010
(In thousands, except per common share - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
NET SALES	\$90,477	\$73,172	\$268,357	\$215,552
COST OF SALES	49,423	41,925	145,034	123,412
GROSS PROFIT	41,054	31,247	123,323	92,140
OPERATING EXPENSES:				
Selling, general, and administrative	25,708	22,480	76,474	61,451
Research and development	5,401	3,865	15,847	10,664
Acquired in-process research and development	3,438	—	3,438	—
Goodwill impairment charge	—	8,344	—	8,344
Total operating expenses	34,547	34,689	95,759	80,459
INCOME (LOSS) FROM OPERATIONS	6,507	(3,442)) 27,564	11,681
OTHER INCOME (EXPENSE):				
Interest income	36	7	52	27
Interest expense	(19)) (95)) (755)) (145)
Other income - net	159	18	238	94
Other income (expense) - net	176	(70)) (465)) (24)
INCOME (LOSS) BEFORE INCOME TAXES	6,683	(3,512)) 27,099	11,657
INCOME TAX EXPENSE (BENEFIT)	2,120	(1,539)) 9,025	3,407
NET INCOME (LOSS)	\$4,563	\$(1,973)) \$18,074	\$8,250
EARNINGS (LOSS) PER COMMON SHARE:				
Basic	\$0.11	\$(0.06)) \$0.47	\$0.23
Diluted	\$0.11	\$(0.06)) \$0.47	\$0.23
AVERAGE COMMON SHARES:				
Basic	41,909	35,293	38,123	35,249
Diluted	42,502	35,293	38,832	35,954

See condensed notes to consolidated financial statements.

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010
(In thousands - unaudited)

	Nine Months Ended September 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$18,074	\$8,250
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,250	10,565
Losses on sales and/or abandonment of property and equipment	3	449
Acquired in-process research and development	3,438	—
Write-off of certain patents and trademarks	59	108
Impairment of goodwill	—	8,344
Amortization of deferred credits	(81) (84
Purchase of trading investments	—	(452
Net unrealized losses on trading investments	—	146
Deferred income taxes	463	(3,075
Stock-based compensation	1,082	950
Tax benefit attributable to appreciation of common stock options exercised	(2,857) (113
Changes in operating assets and liabilities, net of effects from acquisitions:		
Trade receivables	(3,191) (3,242
Employee receivables	(88) 7
Other receivables	(204) (116
Inventories	(5,960) (5,313
Prepaid expenses and other assets	(1,757) (693
Income tax refunds receivable	(367) 71
Trade payables	(4,021) 317
Accrued expenses	2,606	2,541
Advances from employees	501	111
Income taxes payable	6,568	2,499
Deferred compensation payable	124	119
Liabilities related to unrecognized tax positions	(823) (590
Other long-term assets	(87) (63
Other long-term obligations	976	(115
Total adjustments	10,634	12,371
Net cash provided by operating activities	28,708	20,621
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures for:		
Property and equipment	(37,086) (15,592
Patents and trademarks	(1,768) (718
Proceeds from the sale of property and equipment	5	16
Proceeds from sale of marketable securities	—	9,673
Cash paid in acquisitions	(8,250) (96,226

Net cash used in investing activities	(47,099) (102,847)
See condensed notes to consolidated financial statements.		(Continued)	

4

Table of Contents

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010
(In thousands - unaudited)

	Nine Months Ended September 30,	
	2011	2010
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	\$94,800	\$1,351
Borrowings on line of credit	—	1,500
Payments on line of credit	—	(8,500)
Proceeds from issuance of long-term debt	61,507	97,278
Payments on long-term debt	(137,426)	(9,289)
Long-term debt issuance costs	—	(522)
Payment of taxes related to an exchange of common stock	(819)	—
Excess tax benefits from stock-based compensation	2,857	113
Net cash provided by financing activities	20,919	81,931
EFFECT OF EXCHANGE RATES ON CASH	(444)	(540)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,084	(835)
CASH AND CASH EQUIVALENTS:		
Beginning of period	3,735	6,133
End of period	\$5,819	\$5,298
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION—Cash paid during the period (net of capitalized interest of \$264 and \$0, respectively):		
Interest	\$749	\$71
Income taxes	\$3,192	\$4,447
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Property and equipment purchases in accounts payable	\$7,065	\$2,077
Accrued purchase price related to acquisitions	\$2,208	\$500

During the nine months ended September 30, 2011, 50,142 shares of Merit's common stock were surrendered in exchange for Merit's recording of payroll tax liabilities in the amount of approximately \$819,000, related to the exercise of stock options. The shares were valued based upon the closing price of Merit's common stock on the surrender date.

During the nine months ended September 30, 2011, 53,000 shares of Merit's common stock, with a value of approximately \$913,000, were surrendered in exchange for the exercise of stock options.

See condensed notes to consolidated financial statements.

(Concluded)

5

Table of Contents

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, 2011 and 2010 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 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, 2011, and our results of operations and cash flows for the three and nine-month periods ended September 30, 2011 and 2010. The results of operations for the three and nine-month periods ended September 30, 2011 are not necessarily indicative of the results for a full year. 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, 2010 filed with the Securities and Exchange Commission (the “SEC”).

2. Inventories. Inventories are stated at the lower of cost or market. Inventories at September 30, 2011 and December 31, 2010 consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Finished goods	\$32,498	\$30,780
Work-in-process	10,104	7,012
Raw materials	23,955	22,805
Total	\$66,557	\$60,597

3. Reporting Comprehensive Income. The following table presents comprehensive income for the three and nine-month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Net income	\$4,563	\$(1,973)) \$18,074	\$8,250
Interest rate swap, net of tax	(151) —	(708) —
Foreign currency translation	(576) 393	(185) 373
Comprehensive income	\$3,836	\$(1,580)) \$17,181	\$8,623

As of September 30, 2011, accumulated other comprehensive income consisted solely of foreign currency translation adjustments. As of December 31, 2010, accumulated other comprehensive income included approximately \$708,000 (net of tax of \$451,000) related to an interest rate swap and \$152,000 related to foreign currency translation.

4. Stock-based Compensation. Stock-based compensation expense for the three and nine-month periods ended September 30, 2011 and 2010 has been categorized as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Cost of sales	\$69	\$53	\$158	\$149

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-Q

Research and development	24	13	53	42
Selling, general and administrative	343	278	871	759
Stock-based compensation	\$436	\$344	\$1,082	\$950

The excess income tax benefit created from the exercises of stock options was approximately \$4,000 and \$2.9 million for the three

6

Table of Contents

and nine-month periods ended September 30, 2011, respectively, as compared to \$64,000 and \$113,000 for both the three and nine-month periods ended September 30, 2010, respectively. As of September 30, 2011, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$6.5 million and is expected to be recognized over a weighted average period of 3.82 years. During the nine-month periods ended September 30, 2011 and 2010, we granted 844,000 and 100,000 stock awards, respectively. We use the Black-Scholes methodology to value the stock-based compensation expense for options. In applying the Black-Scholes methodology to our outstanding option grants, we used the following assumptions:

	Nine Months Ended September 30,	
	2011	2010
Risk-free interest rate	1.34% - .68%	2.24%
Expected option life	4.2 - 6.0	6.0
Expected price volatility	42.11% - 45.29%	41.40%

For the purpose of determining stock compensation for options, we estimate the average risk-free interest rate using the U.S. Treasury rate in effect as of the date of grant, based on the expected term of the stock option. We estimate the expected term of stock options using the historical exercise behavior of our employees. We estimate the expected price volatility 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.

5. Earnings Per Common Share. The following table sets forth the computation of the number of shares used in calculating basic and diluted net income per share (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, 2011:						
Basic EPS	\$4,563	41,909	\$0.11	\$18,074	38,123	\$0.47
Effect of dilutive stock options and warrants		593			709	
Diluted EPS	\$4,563	42,502	\$0.11	\$18,074	38,832	\$0.47
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		695			770	
Period ended September 30, 2010:						
Basic EPS	\$(1,973)	35,293	\$(0.06)	\$8,250	35,249	\$0.23
Effect of dilutive stock options and warrants		—			705	
Diluted EPS	\$(1,973)	35,293	\$(0.06)	\$8,250	35,954	\$0.23
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		869			1,170	

6. Acquisitions. On September 2, 2011, we entered into an Asset Purchase Agreement with Ash Access Technology, Inc. ("Ash Access"), an Indiana corporation, and AAT Catheter Technologies, LLC ("AAT"), an Indiana limited

liability corporation (collectively "Ash"), to purchase intellectual property rights with respect to various dialysis catheters. We made an initial payment of \$5.0 million to Ash in September of 2011. We are obligated to pay an additional \$1.0 million upon reaching a certain milestone set forth in the purchase agreement and future royalties based on a percentage of related product sales. The acquisition-date fair value of these contingent liabilities has been included as part of the purchase consideration. Acquisition-related costs during the three and nine-month periods ended September 30, 2011, respectively, which are included in selling, general and administrative

7

Table of Contents

expense in the accompanying consolidated statements of operations, were not material. There were no sales or net income related to this acquisition recorded in our consolidated financial statements for the three and nine-month periods ended September 30, 2011. The purchase price was preliminarily allocated as follows (in thousands):

Assets Acquired	
Property and equipment	\$ 73
Intangibles	
Developed technology	3,200
Customer lists	300
Goodwill	2,697
Total assets acquired	6,270
Liabilities Assumed	
Contingent liabilities	1,270
Net assets acquired	\$5,000

With respect to the assets we acquired from Ash, we intend to amortize developed technology over 15 years and customer lists on an accelerated basis over three years. The total weighted-average amortization period for these acquired intangible assets is nine years. The assets and liabilities related to this acquisition are included in our cardiovascular segment.

Pro forma consolidated financial results for the Ash acquisition discussed above have not been included in our consolidated financial results because we believe their effects would not be material.

The goodwill arising from the Ash acquisition discussed above consists largely of the synergies and economies of scale we hope to achieve from combining the acquired assets with our historical operations (see Note 13). We anticipate that the goodwill recognized from this acquisition will be deductible for income tax purposes.

On June 20, 2011, we entered into an Asset Purchase Agreement to acquire the intellectual property rights to certain vena cava filter technology. We made an initial payment of \$1.0 million in June 2011, and we are obligated to pay up to an additional \$3.5 million if certain milestones set forth in the purchase agreement are reached related to further research and development activities and regulatory approval of the vena cava filter. On July 18, 2011, we entered into a Technology License Agreement to acquire the intellectual property rights to certain introducer sheath technology. We made an initial payment of \$1.0 million in July 2011 and are obligated to pay an additional \$1.0 million upon the earlier of the commercialization of the product or the third anniversary of the effective date of the license agreement. The discounted liability of \$938,000 has been reflected in our consolidated balance sheet as a long-term liability as of September 30, 2011. These agreements represented asset acquisitions related to research and development projects and not business combinations. A total charge of approximately \$2.9 million related to these acquired in-process research and development assets has been included in the accompanying consolidated statements of operations for the three and nine-month periods ended September 30, 2011 since technological feasibility of the underlying research and development projects had not yet been reached and such technology had no future alternative use. The primary basis for determining the technological feasibility of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. As of June 30, 2011, we had recorded an increase of \$4.5 million in intangible assets and an increase of \$3.5 million in other long-term liabilities related to the vena cava filter technology acquisition and the initial \$1.0 million payment made in June 2011. Subsequent to the three months ended June 30, 2011, we determined these amounts were recorded in error and corrected the consolidated balance sheet amounts as of September 30, 2011 by recording a corresponding decrease in intangible assets and other long-term liabilities. In addition, the \$1.0 million initial payment (approximately \$627,000 after tax) was recorded as a charge to acquired in-process research and development assets in the accompanying consolidated statements of operations for

the three and nine-month periods ended September 30, 2011. We have concluded that the impact of the error on our consolidated financial statements for the three and six-month periods ended June 30, 2011 is not material, and we do not believe the correction of this error to be material to the consolidated financial statements for the three month period ended September 30, 2011.

On April 6, 2011, we supplemented and amended our Exclusive License, Development and Supply Agreement with Vysera Biomedical Limited (“Vysera”) to include the manufacturing rights for their valve technology. We made an initial payment of \$500,000 in April 2011 and a final payment of \$500,000 in August of 2011. We have recorded the \$1.0 million intangible asset as developed technology for purposes of our consolidated balance sheet and we intend to amortize it over an estimated life of 10 years.

Table of Contents

On September 10, 2010, we completed our acquisition of BioSphere Medical, Inc. (“BioSphere”) in an all-cash merger transaction valued at approximately \$96 million, inclusive of all common equity and Series A Preferred preferences. BioSphere develops and markets embolotherapeutic products for the treatment of uterine fibroids, hypervascularized tumors and arteriovenous malformations. We believe the acquisition of BioSphere gives us a platform technology applicable to multiple therapeutic areas with significant market potential while leveraging existing interventional radiology call points. The gross amount of trade receivables we acquired from BioSphere was approximately \$4.6 million, of which \$51,000 is expected to be uncollectible. Our consolidated financial statements for the three and nine-month periods ended September 30, 2011 reflect sales subsequent to the acquisition date of approximately \$8.0 million and \$22.6 million, respectively, related to our BioSphere acquisition. We report sales and operating expenses related to the BioSphere acquisition in our cardiovascular segment. It is not practical to separately report the earnings related to the BioSphere acquisition, as we cannot split out sales costs related to Biosphere’s products, principally because our sales representatives are selling multiple products (including BioSphere products) in the cardiovascular business segment. As of December 31, 2010, the BioSphere purchase price was allocated as follows (in thousands):

Assets Acquired	
Marketable securities	\$9,673
Trade receivables	4,529
Inventories	5,694
Other assets	1,340
Property and equipment	546
Deferred income tax assets	16,012
Intangibles	
Developed technology	19,000
Customer list	7,900
License agreement	380
Trademark	3,200
Goodwill	34,016
Total assets acquired	102,290
Liabilities Assumed	
Accounts payable	322
Accrued expenses	3,617
Deferred income tax liabilities	729
Liabilities related to unrecognized tax benefits	961
Other liabilities	936
Total liabilities assumed	6,565
Net assets acquired, net of cash acquired of \$274	\$95,725

For the nine months ended September 30, 2011, the goodwill related to the BioSphere acquisition was decreased by approximately \$228,000. The change was primarily due to BioSphere tax adjustments including items related to the BioSphere 2010 income tax return, which was finalized during the third quarter of 2011.

With respect to the BioSphere assets, we intend to amortize developed technology over 15 years, a license agreement over 10 years and customer lists on an accelerated basis over 10 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 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 13.6 years.

In connection with our BioSphere acquisition, we paid approximately \$522,000 in long-term debt issuance costs to Wells Fargo Bank (“Wells Fargo”) for our long-term debt (see Note 10). These costs consist primarily of loan origination fees and legal costs that we intend to amortize over five years, which is the contract term of an unsecured Credit Agreement, dated September 10, 2010 (the “Credit Agreement”) with lenders who are or may become party thereto (collectively, the “Lenders”) and Wells Fargo, as administrative agent for the Lenders. We also incurred approximately \$86,000 of acquisition-related costs during the nine months ended September 30, 2011, respectively, which are included in selling, general and administrative expense in the

Table of Contents

accompanying consolidated statements of operations.

During the fourth quarter of 2010, we terminated several exclusive BioSphere sales distributor agreements in European countries where we already had previously established direct sales relationships. In connection with the termination of these agreements, we agreed to purchase customer lists from the terminated distributors. The total purchase price of the customer lists was approximately \$1.3 million and was allocated to customer lists. We intend to amortize the customer lists on an accelerated basis over 10 years.

On February 19, 2010, we entered into a manufacturing and technology license agreement with a medical device manufacturer for certain medical products. We made an initial payment of \$250,000 in February 2010, a second payment of \$250,000 in May 2010, a third payment of \$250,000 in November 2010 and a final payment of \$250,000 in August of 2011. We have included the \$1.0 million intangible asset in license agreements and intend to amortize the asset over an estimated life of 10 years.

The following table summarizes our unaudited consolidated results of operations for the three and nine-month periods ended September 30, 2010, as well as the unaudited pro forma consolidated results of operations as though the BioSphere acquisition had occurred on January 1, 2010 (in thousands, except per common share amounts):

	Three Months Ended September 30, 2010		Nine Months Ended September 30, 2010	
	As Reported	Pro Forma	As Reported	Pro Forma
Sales	\$73,172	\$78,966	\$215,552	\$236,179
Net income	(1,973) (4,714) 8,250	2,804
Earnings (loss) per common share:				
Basic	(0.06) (0.13) 0.23	0.07
Diluted	(0.06) (0.13) 0.23	0.07

The unaudited pro forma information set forth above is for informational purposes only and should not be considered indicative of actual results that would have been achieved if BioSphere had been acquired at the beginning of 2010, or results that may be obtained in any future period.

7. 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. Our cardiovascular segment also includes the embolotherapeutic products acquired from BioSphere. Our endoscopy segment consists of gastroenterology and pulmonary medical device products which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors. We evaluate the performance of our operating segments based on operating income (loss). Financial information relating to our reportable operating segments and reconciliations to the consolidated totals is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues				
Cardiovascular	\$87,532	\$71,043	\$259,398	\$208,540
Endoscopy	2,945	2,129	8,959	7,012
Total revenues	\$90,477	\$73,172	\$268,357	\$215,552

Operating Income (Loss)

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-Q

Cardiovascular	\$7,405	\$6,032	\$30,385	\$23,210
Endoscopy	(898) (9,474) (2,821) (11,529
Total operating income (loss)	\$6,507	\$(3,442) \$27,564	\$11,681

8. Recent Accounting Pronouncements. In September 2011, the Financial Accounting Standards Board ("FASB") issued authoritative guidance related to testing goodwill for impairment. This guidance provides that entities may first assess qualitative

Table of Contents

factors to determine whether it is necessary to perform the two-step goodwill impairment test. If the qualitative assessment results in a more than 50% likely result that the fair value of a reporting unit is less than the carrying amount, then the entity must continue to apply the two-step impairment test. If the entity concludes the fair value exceeds the carrying amount, then neither of the two steps in the goodwill impairment test is required. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In June 2011, the FASB issued authoritative guidance on the presentation of comprehensive income. This guidance specifies that an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. It also does not change the presentation of related tax effects, before related tax effects, or the portrayal or calculation of earnings per share. This guidance is to be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In December 2010, the FASB issued authoritative guidance which modifies the requirements of step one of the goodwill impairment test for reporting units with zero or negative carrying amounts. This guidance modifies step one so that for those reporting units, an entity is required to perform step two of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. The adoption of this guidance did not have a material effect on our consolidated financial statements.

In December 2010, the FASB issued authoritative guidance to address diversity in practice about pro forma revenue and earnings disclosure requirements. This guidance specifies that if a public entity presents comparative financial statements, the entity shall disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. This guidance also expands the supplemental pro forma disclosures to include a description of the nature and amount of material nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This guidance is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. We intend to apply these required disclosures to any future business combinations.

In January 2010, the FASB issued additional authoritative guidance on fair value disclosures. The new guidance clarifies two existing disclosure requirements and requires two new disclosures as follows: (1) a “gross” presentation of activities (purchases, sales, and settlements) within the Level 3 rollforward reconciliation, which will replace the “net” presentation format; and (2) detailed disclosures about the transfers in and out of Level 1 and 2 measurements. This guidance is effective for the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 rollforward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. We adopted the fair value disclosure guidance on January 1, 2010, except for the gross presentation of the Level 3 rollforward information which we adopted on January 1, 2011. The adoption of this guidance did not have a material effect on our consolidated

financial statements.

9. **Income Taxes.** Our effective tax rate for the three months ended September 30, 2011 was 31.7%. For the corresponding period of 2010, we recorded an income tax benefit, resulting in an effective tax rate of 43.8%. The decrease in the effective tax rate for the three months ended September 30, 2011 compared to the effective tax benefit rate for the corresponding period of 2010 was primarily related to the fact that our U.S. operations, which are taxed at a higher rate than our foreign operations, incurred a pre-tax loss in the third quarter of 2010. Benefits related to the expiration of statutes of limitation with respect to uncertain tax positions also had an impact on the effective tax rate for the three months ended September 30, 2011. For the nine months ended September 30, 2011, our effective tax rate was 33.3%, compared to 29.2% for the corresponding period of 2010. The increase in the effective tax rate for the nine-month period ended September 30, 2011, when compared to the corresponding period of 2010, was primarily related to the increased profit of our U.S. operations which are taxed at a higher rate than our foreign operations (primarily our Irish operations).

10. **Long-Term Debt.** In connection with our acquisition of BioSphere, we entered into the Credit Agreement with the Lenders and Wells Fargo. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate principal amount of \$125 million. Wells Fargo has also agreed to make swing line loans from time to time through the

11

Table of Contents

maturity date of September 10, 2015 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate credit commitment.

On September 10, 2015, all principal, interest and other amounts outstanding under the Credit Agreement are payable in full. At any time prior to the maturity date, we may repay any amounts owing under all revolving credit loans and all swing line loans in whole or in part, without premium or penalty.

Revolving credit loans made under the Credit Agreement bear interest, at our election, at either (i) the base rate (described below) plus 0.25%, (ii) the London Inter-Bank Offered Rate (“LIBOR”) Market Index Rate (as defined in the Credit Agreement) plus 1.25%, or (iii) the LIBOR Rate (as defined in the Credit Agreement) plus 1.25%. Swing line loans bear interest at the LIBOR Market Index Rate plus 1.25%. Interest on each loan featuring the base rate or the LIBOR Market Index Rate is due and payable on the last business day of each calendar month; interest on each loan featuring the LIBOR Rate is due and payable on the last day of each interest period selected by us when selecting the LIBOR Rate as the benchmark for interest calculation. For purposes of the Credit Agreement, the base rate means the highest of (i) the prime rate (as announced by Wells Fargo), (ii) the federal funds rate plus 0.50%, and (iii) LIBOR for an interest period of one month plus 1.0%.

The Credit Agreement contains covenants, representations and warranties and other terms, that are customary for revolving credit facilities of this nature. In this regard, the Credit Agreement requires us to maintain a leverage ratio, an EBITDA ratio, and a minimum consolidated net income, and limits the amount of annual capital expenditures we can incur. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including limitations respecting: the incurrence of indebtedness, the creation of liens on our property, mergers or similar combinations or liquidations, asset dispositions, investments in subsidiaries, and other provisions customary in similar types of agreements. As of September 30, 2011, we were in compliance with all financial covenants set forth in the Credit Agreement.

As of September 30, 2011, we had outstanding borrowings of approximately \$5.6 million under the Credit Agreement, with available borrowings of approximately \$119.4 million, based on the leverage ratio in the terms of the Credit Agreement. As of September 30, 2011, our interest rate under the Credit Agreement was a variable rate of 1.62%.

11. Derivatives.

Interest Rate Swap. On October 25, 2010, we entered into a \$55 million pay-fixed, receive-variable interest rate swap with Wells Fargo at a fixed interest rate of 2.73%. The variable portion of the interest rate swap is tied to the one-month LIBOR rate (the benchmark interest rate). The interest rates under both the interest rate swap and the underlying debt are reset, the swap is settled with the counterparty, and interest is paid, on a monthly basis. The interest rate swap was scheduled to expire on September 10, 2015. This interest rate swap had qualified as a cash flow hedge. During the three and nine-month periods ended September 30, 2011, the amount reclassified from accumulated other comprehensive income to earnings due to hedge effectiveness was approximately \$5,000 and \$73,000, respectively, which is included in interest expense in the accompanying consolidated statements of operations. On July 7, 2011, we terminated our interest rate swap agreement, which resulted in a cash receipt of and gain of approximately \$28,000 upon final settlement.

Foreign Currency Forward Contracts. On August 31, 2011, we forecasted a net exposure for September 30, 2011 (representing the difference between Euro and Great Britain Pound (“GBP”)-denominated receivables and Euro-denominated payables) of approximately 558,000 Euros and 345,000 GBPs. In order to partially offset such risks, on August 31, 2011, we entered into a 30-day forward contract for the Euro and GBP with notional amounts of approximately 558,000 Euros and 345,000 GBPs. 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. During the three and nine-month periods ended September 30, 2011 and 2010, the effect on our consolidated statement of operations of all forward contracts and the fair value of our open positions was not material.

12. Fair Value Measurements. The fair value of a financial instrument is the amount that could be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets are marked to bid prices and financial liabilities are marked to offer prices. Fair value measurements do not include transaction costs. A fair value hierarchy is used to prioritize the quality and reliability of the information used to determine fair values. Categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. The fair value hierarchy is defined into the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market

Table of Contents

The following table identifies our financial assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2010 (in thousands):

Description	Total Fair Value at December 31, 2010	Fair Value Measurements Using		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant Unobservable inputs (Level 3)
Interest rate swap (1)	\$1,159	—	\$1,159	—

(1) The fair value of the interest rate swap is determined based on forward yield curves.

As of September 30, 2011, there were no financial assets or liabilities carried at fair value measured on a recurring basis. During the three and nine-month periods ended September 30, 2011, we had write-offs of approximately \$42,000 and \$59,000, respectively, compared to approximately \$8.4 million and \$8.5 million, respectively, for the corresponding three and nine-month periods ended September 30, 2010, related to the measurement of non-financial assets at fair value on a non-recurring basis subsequent to their initial recognition. Of the total write-offs for the three and nine-month periods ended September 30, 2010, approximately \$8.3 million related to the impairment of our goodwill balance related to our endoscopy reporting unit. The fair value of goodwill was measured using Level 3 inputs. Subsequent to this impairment charge, there is no goodwill remaining related to the endoscopy reporting unit.

The carrying amount of cash and 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.

13. Goodwill and Intangible Assets. The changes in the carrying amount of goodwill for the nine months ended September 30, 2011, are as follows (in thousands):

Goodwill balance at January 1	2011 \$58,675
Changes as the result of acquisitions (see Note 6)	2,469
Goodwill balance at September 30	\$61,144

Intangible assets at September 30, 2011 and December 31, 2010, consisted of the following (in thousands):

	September 30, 2011			December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$6,190	\$(1,632)	\$4,558	\$4,631	\$(1,445)	\$3,186
Distribution agreement	2,426	(835)	1,591	2,426	(641)	1,785
License agreements	1,983	(414)	1,569	1,833	(352)	1,481
Trademark	5,767	(922)	4,845	5,761	(636)	5,125
Developed technology	40,386	(4,125)	36,261	36,574	(2,301)	34,273
In-process technology	400	—	400	400	—	400
Covenant not to compete	315	(98)	217	315	(67)	248

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-Q

Customer lists	14,308	(5,205) 9,103	13,973	(3,287) 10,686
Royalty agreements	267	(267) —	267	(267) —
Total	\$72,042	\$(13,498) \$58,544	\$66,180	\$(8,996) \$57,184

13

Table of Contents

The aggregate amortization expense was approximately \$1.4 million and \$4.5 million for the three and nine-month periods ended September 30, 2011, respectively, and approximately \$1.0 million and \$2.3 million for the three and nine-month periods ended September 30, 2010, respectively.

Estimated amortization expense for our intangible assets for the next five years consisted of the following (in thousands):

Remaining 2011	\$ 1,507
2012	5,306
2013	5,114
2014	4,777
2015	4,514

14. **Equity.** On June 22, 2011, Merit completed an equity public offering of 5,520,000 shares of common stock and received proceeds of approximately \$87.7 million, which is net of approximately \$4.6 million in underwriting discounts and commissions. We incurred approximately \$127,000 in other direct costs in connection with this equity offering. In addition to the net proceeds of the public equity offering, we received approximately \$6.8 million in cash related to the exercise of options to purchase approximately 983,000 shares of common stock and approximately \$2.9 million in tax benefits attributable to appreciation of these options exercised during the nine months ended September 30, 2011.

15. **Stock Split.** On April 21, 2011, our Board of Directors authorized a 5-for-4 forward stock split of our common stock to be effected in the form of a stock dividend of one share of common stock for every four shares of common stock outstanding on the record date. On May 5, 2011, we completed the forward stock split through a stock dividend to shareholders of record as of May 2, 2011. The Board of Directors also made corresponding adjustments to the number of shares subject to, and the exercise price of, outstanding options and other rights to acquire shares of common stock. All earnings per common share and common share data set forth in the foregoing consolidated financial statements (and condensed notes thereto) have been adjusted to reflect the split.

Table of Contents

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 management for future operations, any statements concerning proposed new products or services, any statements regarding the 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. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that any such expectation or any forward-looking statement will prove to be correct. Our actual results will 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 by our current debt agreements; possible infringement of our technology or the assertion that our technology infringes the rights of other parties; 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; laws targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in, or 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, including the BioSphere acquisition; fluctuations in Euro and GBP exchange rates; 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; failure 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 Merit; 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 our Annual Report on Form 10-K for the year ended December 31, 2010 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. Actual results will differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates. Additional factors that may have a direct bearing on our operating results are discussed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2010.

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 this Quarterly Report on Form 10-Q.

We design, develop, manufacture and market single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases and includes the embolotherapeutic products we acquired through our acquisition of BioSphere. Our endoscopy segment consists of gastroenterology and pulmonology medical devices which assist in the palliative treatment of expanding esophageal, tracheobronchial and biliary strictures caused by malignant tumors.

Table of Contents

For the quarter ended September 30, 2011, we reported revenues of \$90.5 million, up 24% from the three months ended September 30, 2010 of \$73.2 million. Revenues for the nine months ended September 30, 2011 were a record \$268.4 million, compared with \$215.6 million for the first nine months of 2010, a gain of 24%.

Our base business sales (which exclude BioSphere's embolization device sales) increased 15.1% for the third quarter of 2011, compared to the third quarter of 2010. Our base business sales for the nine months ended September 30, 2011 increased 14.8% when compared to the corresponding period for 2010. Sales of BioSphere embolization devices accounted for an increase of 8.9% and 9.8% of sales for the three and nine-month periods ended September 30, 2011, respectively.

Gross profits were 45.4% and 46.0% of sales for the three and nine-month periods ended September 30, 2011, respectively, compared to 42.7% of sales for both the three and nine-month periods ended September 30, 2010, respectively. The improvement in gross profits for both periods was primarily due to the addition of higher-margin BioSphere product sales and higher prices and unit sales through our distribution system in China.

During the quarter ended September 30, 2011, we recorded a charge of \$3.4 million for acquired in-process research and development, primarily related to the acquisition of intellectual property for a vena cava filter of \$1.0 million, flexible sheath technology of approximately \$1.9 million, and the write-off of our coating technology of \$500,000.

Net income for the quarter ended September 30, 2011 was \$4.6 million, or \$.11 per share, compared to a loss of (\$2.0) million, or (\$0.06) per share, for the corresponding period of 2010. Net income for the nine-month period ended September 30, 2011 was \$18.1 million, or \$0.47 per share, compared to \$8.3 million, or \$0.23 per share, for the corresponding period of 2010. When compared to the prior year periods and excluding the non-recurring charges for the BioSphere transaction costs, severance costs and goodwill impairment recognized in the three and nine-month periods ended September 30, 2010, net income for the three and nine-month periods ended September 30, 2011 was favorably affected by higher sales and gross margins, which was partially offset by higher selling, general and administrative expenses, increased research and development expenses and acquired in-process research and development of \$3.4 million.

Our business continues to grow in most of our geographic regions and product groups. We plan to continue to expand our product offerings in strategic foreign markets, as the sales growth in these international markets are growing much more rapidly than our U.S. market. Our international sales for the nine months ended September 30, 2011 represented 35% of our total sales, compared to 31% of our total sales for the comparable period of 2010. We believe the investments we have made over the past few years in acquisitions and internally-developed products are paying off. Our acquisitions are providing best-in-class products as well as the pull-through of other core products we sell, which has helped accelerate our sales growth.

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, 2011 and 2010:

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2011	2010	2011	2010	
Sales	100.0	% 100.0	% 100.0	% 100.0	%
Gross profit	45.4	42.7	46.0	42.7	
Selling, general and administrative expenses	28.4	30.7	28.5	28.5	
Research and development cost	6.0	5.3	5.9	4.9	

Edgar Filing: MERIT MEDICAL SYSTEMS INC - Form 10-Q

Acquired in-process research and development	3.8	—	1.3	—
Goodwill impairment charge	—	11.4	—	3.9
Income (loss) from operations	7.2	(4.7) 10.3	5.4
Other income (expense)	0.2	(0.1) (0.2) —
Net income (loss)	5.0	(2.7) 6.7	3.8

Sales. Sales for the three months ended September 30, 2011 increased by 24%, or approximately \$17.3 million, compared to the corresponding period of 2010. Sales for the nine months ended September 30, 2011 increased by 24%, or approximately \$52.8 million, compared to the corresponding period of 2010. Listed below are the sales by business segment for the three and nine-

Table of Contents

month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	% Change	2011	2010	% Change	2011	2010
Cardiovascular						
Stand-alone devices	19	% \$25,514	\$21,391	17	% \$76,312	\$65,138
Custom kits and procedure trays	6	% 22,947	21,675	11	% 68,878	62,054
Inflation devices	5	% 16,165	15,367	9	% 50,564	46,489
Catheters	34	% 14,929	11,115	23	% 41,037	33,364
Embolization devices	433	% 7,969	1,495	1,412	% 22,600	1,495
Total	23	% 87,524	71,043	24	% 259,391	208,540
Endoscopy						
Endoscopy devices	39	% 2,953	2,129	28	% 8,966	7,012
Total	24	% \$90,477	\$73,172	24	% \$268,357	\$215,552

Cardiovascular Sales. Cardiovascular sales growth of 23% for the three months ended September 30, 2011, and 24% for the nine months ended September 30, 2011, when compared to the corresponding periods of 2010, was primarily due to an increase in sales of BioSphere embolization products of \$6.5 million and \$21.1 million, respectively, and an increase in sales of stand-alone devices for the three and nine-month periods ended September 30, 2011. Sales were also favorably affected by increased catheter sales (particularly our Prelude® sheath product line, aspiration catheter product line and micro catheter product line), sales of custom kits and procedure trays and inflation device sales.

Endoscopy Sales. Endoscopy sales growth of 39% for the three months ended September 30, 2011, and 28% for the nine months ended September 30, 2011, when compared to the corresponding periods of 2010, was primarily due to an increase in sales of our Aero® Tracheobronchial stent.

Gross Profit. Gross profit was 45.4% and 46.0% of sales for the three and nine-month periods ended September 30, 2011, respectively, compared to 42.7% of sales for both the three and nine-month periods ended September 30, 2010. The improvement in gross profit for both periods was primarily due to the addition of higher-margin BioSphere products and higher prices and unit sales through our distribution system in China.

Operating Expenses. Selling, general and administrative expenses decreased to 28.4% of sales for the three months ended September 30, 2011, compared with 30.7% of sales for the three months ended September 30, 2010. Selling, general and administrative expenses was 28.5% of sales for both the nine-month periods ended September 30, 2011 and 2010. Selling, general and administrative expenses for the three and nine-month periods ended September 30, 2010, adjusted for non-recurring BioSphere transactions costs and acquisition severance costs, would have been 26.9% and 26.7%, respectively. The increase in selling, general and administrative expenses for both periods in 2011 was primarily related to the addition of sales and marketing employees, trade shows, commissions and amortization of intangibles relating to the BioSphere acquisition and starting up our Chinese distribution system.

Research and Development Expenses. Research and development expenses increased to 6.0% of sales for the three months ended September 30, 2011, compared with 5.3% of sales for the three months ended September 30, 2010. Research and development expenses increased to 5.9% of sales for the nine months ended September 30, 2011, compared to 4.9% of sales for the nine months ended September 30, 2010. The increase in research and development expenses for both 2011 periods related primarily to additional regulatory costs incurred for the start-up of Merit's HiQuality clinical trial, seeking product regulatory approvals from the FDA and international regulatory agencies, and

the development of several new products for Merit's endoscopy product line.

During the quarter ended September 30, 2011, we recorded a charge of \$3.4 million for acquired in-process research and development, primarily related to the acquisition of intellectual property for a vena cava filter of \$1.0 million, flexible sheath technology of approximately \$1.9 million, and the write-off of our coating technology of \$500,000.

Operating Income (Loss). The following table sets forth our operating income or loss by business segment for the three and

17

Table of Contents

nine-month periods ended September 30, 2011 and 2010 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Operating Income (Loss)				
Cardiovascular	\$7,405	\$6,032	\$30,385	\$23,210
Endoscopy	(898) (9,474) (2,821) (11,529
Total operating income (loss)	\$6,507	\$(3,442) \$27,564	\$11,681

Cardiovascular Operating Income. For the three months ended September 30, 2011, we reported income from operations of approximately \$7.4 million from our cardiovascular business segment, compared to income of approximately \$6.0 million for the corresponding period of 2010. For the nine months ended September 30, 2011, we reported income from operations of approximately \$30.4 million from our cardiovascular business segment, compared to income of approximately \$23.2 million for the corresponding period in 2010. When compared to the prior year periods, the operating income for the three and nine-month periods ended September 30, 2011 was favorably affected by higher sales and gross margins, and was negatively affected by higher selling, general and administrative expenses, research and development expenses and acquired in-process research and development.

Endoscopy Operating Loss. For the three months ended September 30, 2011, we reported a loss from operations of approximately \$898,000 from our endoscopy business segment, compared to a loss of approximately \$9.5 million for the corresponding period of 2010. For the nine months ended September 30, 2011, we reported a loss from operations of approximately \$2.8 million from our endoscopy business segment, compared to a loss of approximately \$11.5 million for the corresponding period of 2010. Absent a goodwill impairment charge of approximately \$8.3 million that we recognized during the three-month period ended September 30, 2010, the net loss from operations for the three and nine month-periods ended September 30, 2010 would have been approximately \$1.1 million and \$3.2 million, respectively. The decrease in operating loss for the three and nine-month periods ended September 30, 2011, when compared to the corresponding periods of 2010, was favorably affected by higher sales and gross margins, and was negatively affected by higher research and development expenses and selling, general and administrative expenses.

Other Income (Expense). Other income for the three months ended September 30, 2011 was approximately \$176,000, compared to other expense of approximately (\$70,000) for the corresponding period in 2010. The net increase in other income for the three-month period ended September 30, 2011 was primarily the result of a decrease in interest expense associated with a lower long-term debt balance and an increase in foreign exchange transaction gains, when compared to the comparable period in 2010. Other expense for the nine months ended September 30, 2011 was approximately (\$465,000), compared to other expense of approximately (\$24,000) for the corresponding period in 2010. The increase in other expense for the nine months ended September 30, 2011 was principally the result of interest expense related to the long-term debt balance incurred in connection with the acquisition of BioSphere in September of 2010, when compared to the corresponding period in 2010.

Income Taxes. Our income tax expense for the three months ended September 30, 2011 reflects an effective tax rate of 31.7%. For the comparable period of 2010, we recorded an income tax benefit, resulting in an effective tax rate of 43.8%. The decrease in the effective tax rate for the three months ended September 30, 2011 compared to the effective tax benefit rate for the corresponding period of 2010 was primarily related to the fact that our U.S. operations, which are taxed at a higher rate than our foreign operations, incurred a pre-tax loss in the third quarter of 2010. Benefits related to the expiration of statutes of limitation with respect to uncertain tax positions also had an impact on the effective tax rate for the three months ended September 30, 2011. For the nine months ended September 30, 2011, our effective tax rate was 33.3%, compared to 29.2% for the corresponding period of 2010. The increase in the effective tax rate for the nine-month period ended September 30, 2011, when compared to the corresponding period of 2010,

was primarily related to the increased profit of our U.S. operations which are taxed at a higher rate than our foreign operations (primarily our Irish operations).

Net Income. Net income for the quarter ended September 30, 2011 was \$4.6 million, or \$.11 per share, compared to a loss of (\$2.0) million, or (\$0.06) per share, for the corresponding period of 2010. Net income for the nine-month period ended September 30, 2011 was \$18.1 million, or \$0.47 per share, compared to \$8.3 million, or \$0.23 per share, for the corresponding period of 2010. When compared to the prior year periods and excluding the non-recurring charges for the BioSphere transaction costs, severance costs and goodwill impairment recognized in the three and nine-month periods ended September 30, 2010, net income for the three and nine-month periods ended September 30, 2011 was favorably affected by higher sales and gross margins, but were negatively affected by higher selling, general and administrative expenses, increased research and development expenses and

Table of Contents

acquired in-process research and development expenses of \$3.4 million.

Liquidity and Capital Resources

On June 22, 2011, we completed our first equity offering since 1992 of 5,520,000 shares of common stock and received proceeds of \$87.7 million, which is net of approximately \$4.6 million in underwriting discounts and commissions (the "Equity Offering"). We incurred approximately \$127,000 in other direct costs in connection with the Equity Offering. In the short term, we used the proceeds of the Equity Offering to pay down our debt and reduce interest costs. In the longer term, we intend to use the portion of our credit facility that was repaid with the proceeds of the Equity Offering to invest in capacity and expansion, new products and other business development opportunities. In addition to the proceeds of the Equity Offering, we received approximately \$6.8 million in cash related to the exercise of options to acquire approximately 983,000 shares of common stock and approximately \$2.9 million in tax benefits attributable to appreciation of the options exercised during the nine months ended September 30, 2011.

Our working capital as of September 30, 2011 and December 31, 2010 was \$75.7 million and \$72.1 million, respectively. As of September 30, 2011, we had a current ratio of 2.6 to 1.

During the nine months ended September 30, 2011, our inventory balances increased by approximately \$6.0 million, from \$60.6 million at December 31, 2010 to \$66.6 million at September 30, 2011. The increase was primarily the result of record sales for nine-months ended September 30, 2011 and a \$2.0 million increase in raw materials related to maintaining a one-year supply of resins.

On September 10, 2010, we entered into the Credit Agreement with the Lenders and Wells Fargo. As of September 30, 2011, Wells Fargo was the only bank involved in the Credit Agreement. Pursuant to the terms of the Credit Agreement, the Lenders have agreed to make revolving credit loans up to an aggregate principal amount of \$125 million. Wells Fargo has also agreed to make swing line loans from time to time through the maturity date of September 10, 2015 in amounts equal to the difference between the amounts actually loaned by the Lenders and the aggregate credit commitment. The Credit Agreement contains covenants, representations and warranties and other terms, that are customary for revolving credit facilities of this nature. In this regard, the Credit Agreement requires us to maintain a leverage ratio, an EBITDA ratio, and a minimum adjusted consolidated net income and limits the amount of annual capital expenditures we can incur. Additionally, the Credit Agreement contains various negative covenants with which we must comply, including limitations respecting: the incurrence of indebtedness, the creation of liens on our property, mergers or similar combinations or liquidations, asset dispositions, investments in subsidiaries, and other provisions customary in similar types of agreements. As of September 30, 2011, we were in compliance with all financial covenants set forth in the Credit Agreement.

As of September 30, 2011, we had outstanding borrowings of approximately \$5.6 million under the Credit Agreement, with available borrowings of approximately \$119.4 million, based on the leverage ratio in the terms of the Credit Agreement. Our interest rate under the Credit Agreement as of September 30, 2011, was a variable floating rate of 1.62%. In July 2011, we used \$55.0 million of the proceeds from the Equity Offering to pay down the outstanding balance on our Credit Agreement, and we terminated our interest rate swap agreement, which resulted in a cash receipt of and gain of approximately \$28,000 upon final settlement.

Historically, we have incurred significant expenses in connection with new facilities, production automation, product development and the introduction of new products. Over the last two years, we spent a substantial amount of cash in connection with our acquisition of certain assets and product lines (\$96.0 million to acquire BioSphere in September 2010 and \$46.2 million to acquire the assets of Alveolus, Inc. and Hatch Medical, L.L.C., among other transactions, during 2009). We plan to construct three new production facilities over the next two years in South

Jordan, Utah, Galway, Ireland, and Pearland, Texas and a parking terrace in South Jordan, Utah, with total anticipated costs of approximately \$72.0 million. As of September 30, 2011, we had incurred total costs of approximately \$24.9 million with respect to those construction projects. In the event we pursue and complete significant transactions or acquisitions in the future, additional funds will likely be required to meet our strategic needs, which may require us to raise additional funds in the debt or equity markets. We currently believe that our existing cash balances, anticipated future cash flows from operations, sales of equity, and existing lines of credit and committed debt financing will be adequate to fund our current and currently planned future operations for the next twelve months and the foreseeable future.

Table of Contents

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical Accounting Policies

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:

Inventory Obsolescence Reserve. 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 a reserve for any slow-moving finished goods 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, 2010 and 2009, respectively, we provided on an annual basis an obsolescence reserve expense of between \$1.9 million to \$1.5 million and have written off against such reserves between \$1.1 million and \$1.3 million on an annual basis. Based on this historical trend, we believe that the amount included in our obsolescence reserve represents an accurate estimate of the 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. packers 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. The allowance is 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 share-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. Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect our management’s best assessment of future taxes to be paid. Significant judgment and estimates are required in determining the consolidated income tax expense. Deferred income taxes arise from temporary differences between

the tax and financial statement recognition of revenue and expense. In evaluating our ability to recover deferred tax assets, we consider projected future taxable income and recent financial operations. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we are using to manage the underlying business.

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 benefits 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. Tax laws are subject to varied interpretations, and we have taken positions related to certain matters where the laws are subject to interpretation.

Table of Contents

Goodwill and Intangible Assets Impairment. 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 based on discounted future cash flows. 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 the implied fair value of that goodwill. This analysis requires significant judgments, 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.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that its 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our principal market risk relates to changes in the value of the Euro and Great Britain Pound (“GBP”) relative to the value of the U.S. Dollar. We also have a limited market risk relating to the Chinese Yuan, Hong Kong Dollar and the Swedish and Danish Kroner. Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the three months ended September 30, 2011, a portion of our revenues (\$13.2 million, representing approximately 14.6% of aggregate revenues), was attributable to sales that were denominated in foreign currencies. All other international sales were denominated in U.S. Dollars. Certain of our expenses for the quarter ended September 30, 2011 were also denominated in foreign currencies, which partially offset risks associated with fluctuations of exchange rates between foreign currencies on the one hand, and the U.S. Dollar on the other hand. During the three months ended September 30, 2011, the exchange rate between our foreign currencies against the U.S. Dollar resulted in an increase in our gross revenues of approximately \$943,000, or 1.0%, and an increase in cost of goods sold of approximately \$902,000, or a decrease of 0.43% in gross profit. The decrease in gross profits was the result of an increase in our Irish manufacturing expenses which are primarily denominated in Euros.

On August 31, 2011, we forecasted a net exposure for September 30, 2011 (representing the difference between Euro and GBP-denominated receivables and Euro-denominated payables) of approximately 558,000 Euros and 345,000 GBPs. In order to partially offset such risks, on August 31, 2011, we entered into a 30-day forward contract for the Euro and GBP with notional amounts of approximately 558,000 Euros and 345,000 GBPs. 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. During the three and nine months ended September 30, 2011 and 2010, the effect on the consolidated statement of operations of all forward contracts and the fair value of our open positions was not material.

As discussed in Note 10 to our consolidated financial statements, as of September 30, 2011, we had outstanding borrowings of approximately \$5.6 million under the Credit Agreement. Accordingly, our earnings and after-tax cash flow are affected by changes in interest rates. In the event of an adverse change in interest rates, our management could take actions to mitigate our interest rate exposure through an interest rate swap agreement. 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.

ITEM 4. CONTROLS AND PROCEDURES

(a) 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, 2011. 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

Table of Contents

decisions regarding required disclosure.

(b) Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2011, 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).

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are subject to certain legal actions which we consider routine to our business activities. As of September 30, 2011, our management concluded, after consultation with legal counsel, that the ultimate outcome of such legal matters is not likely to have a material adverse effect on our financial position, liquidity or results of operations.

ITEM 1A. RISK FACTORS

In addition to other information set forth in this Report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2010, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on 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.

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, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Operations, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to the Consolidated Financial Statements

Table of Contents

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 8, 2011

/s/ FRED P. LAMPROPOULOS
FRED P. LAMPROPOULOS
PRESIDENT AND CHIEF EXECUTIVE OFFICER

Date: November 8, 2011

/s/ KENT W. STANGER
KENT W. STANGER
CHIEF FINANCIAL OFFICER