

MERIT MEDICAL SYSTEMS INC

Form 10-Q

November 09, 2018

MERIT MEDICAL SYSTEMS INC0000856982Large Accelerated

Filer2018Q3falseFALSEFALSE2018-09-30--12-312,0111,76993,68072,42046,08838,1275,0005,000——100,000100,00054,8
years2.19.9159.915——00008569822018-01-012018-09-30xbrli:shares00008569822018-11-05iso4217:USD00008569822018

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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, 2018**

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 (IRS Employer
jurisdiction of Identification

incorporation No.)
 or
 organization)

1600 West Merit Parkway, South Jordan, Utah 84095

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(801) 253-1600**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large Accelerated Filer <input checked="" type="checkbox"/>	Accelerated Filer <input type="checkbox"/>	Non-Accelerated Filer <input type="checkbox"/>	Smaller Reporting Company <input type="checkbox"/>	Emerging Growth Company <input type="checkbox"/>
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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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	54,833,602
Title or class	Number of Shares Outstanding at November 5, 2018

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SUBSIDIARIES**

CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2018 AND DECEMBER 31,
2017

(In thousands)

September 30, 2018	December 31, 2017
(unaudited)	
ASSETS	
CURRENT ASSETS:	
Cash and cash equivalents	\$ 51,955
Trade receivables — net of allowance for uncollectible accounts — 2018 and 2017	\$ 105,536
Other receivables	8,903
Inventory	155,288
Prepaid expenses and other assets	9,096
Prepaid income taxes	3,225
Income tax refund receivables	1,043
Total current assets	316,121

PROPERTY
AND
EQUIPMENT:

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Land and land improvements	26,926	19,877
Buildings	50,880	147,356
Manufacturing equipment	211,215	197,651
Furniture and fixtures	53,869	49,528
Leasehold improvements	33,365	31,161
Construction-in-progress	48,166	32,896
Total property and equipment	724,421	478,469
Less accumulated depreciation	(404,406)	(185,649)
Property and equipment — net	319,925	292,820
OTHER ASSETS:		
Intangible assets:		
Developed technology — net of accumulated amortization — 2018 — \$93,680 and 2017 — \$72,420	274,240	167,771
Other — net of accumulated amortization — 2018 — \$46,088 and 2017 — \$38,127	64,565	59,553
Goodwill	249,013	238,147
Deferred income tax assets	2,254	2,359
Other assets	61,927	35,040

Total of assets	1,309,883	502,870
TOTAL	1,309,883	\$ 1,111,811

See condensed notes to consolidated financial statements.

(continued)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND
SUBSIDIARIES**

CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2018 AND DECEMBER 31,
2017

(In thousands)

September 30, 2018	December 31, 2017
-------------------------------	------------------------------

(unaudited)

**LIABILITIES
AND
STOCKHOLDERS'
EQUITY**CURRENT
LIABILITIES:

Trade payables	50,697	\$	34,931
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Accrued expenses	65,530	58,932
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Current portion of 22,000 long-term debt	19,459
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Income taxes payable	1,598	2,298
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Total current liabilities	139,825	115,620
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LONG-TERM DEBT	186,867	259,013
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DEFERRED INCOME TAX	23,102	23,289
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LIABILITIES

LONG-TERM INCOME TAXES PAYABLE	4,846	4,846
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LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	2,746	2,746
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DEFERRED COMPENSATION PAYABLE	11,181
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DEFERRED CREDITS	7,796	2,403
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	14,814	16,379
--	--------	--------

OTHER
LONG-TERM
OBLIGATIONS

Total liabilities	435,477
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COMMITMENTS
AND
CONTINGENCIES
(Notes 5,
10,
11,
and
14)

STOCKHOLDERS'
EQUITY:

Preferred stock
— 5,000 shares authorized as of September 30, 2018 and December 31, 2017; no shares issued

—

Common stock, no par value; shares authorized — 2018 and 2017 - 100,000; issued and outstanding as of September 30, 2018 - 54,802 and December 31, 2017 -

353,392

50,248			
Retained earnings	321,408		
Accumulated other comprehensive income	1,534		
Total stockholders' equity	676,334		
TOTAL	1,309,883	\$	1,111,811

See condensed notes to consolidated financial statements. (concluded)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**

CONSOLIDATED STATEMENTS OF INCOME

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

(In thousands, except per share amounts - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
NET SALES	221,659	\$ 179,337	\$ 649,504	\$ 536,955
COST OF SALES	19,620	98,823	359,400	296,358
GROSS PROFIT	202,039	80,514	290,104	240,597
OPERATING EXPENSES:				
Selling, general and administrative	66,382	54,716	200,389	169,896
Research and development	4,525	12,838	44,163	38,676
Intangible asset impairment charge	657	—	657	—
Contingent consideration expense (benefit)	(661)	20	(442)	39
Acquired in-process research and development	754	12,061	382	12,136
Total operating expenses	80,978	79,635	245,149	220,747
INCOME FROM OPERATIONS	121,061	879	44,955	19,850
OTHER INCOME (EXPENSE):				
Interest income	359	94	847	266
Interest expense	(2,329)	(1,590)	(8,064)	(5,935)
Gain on bargain purchase	—	(778)	—	10,796

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Other income (expense)	(810)	(429)	(376)	
- net				
Other income (expense)	(3,084)	(7,646)	4,751	
— net				
INCOME (LOSS) BEFORE INCOME TAXES	(2,205)	37,309	24,601	
INCOME TAX EXPENSE	1,364	4,481	3,884	
NET INCOME (LOSS)	\$ (3,569)	\$ 32,828	\$ 20,717	
EARNINGS PER COMMON SHARE:				
Basic 0.31	\$ (0.07)	\$ 0.64	\$ 0.43	
Diluted 0.30	\$ (0.07)	\$ 0.62	\$ 0.42	
AVERAGE COMMON SHARES:				
Basic 431	50,150	51,434	48,332	
Diluted 431	51,599	53,096	49,555	
See condensed notes to consolidated financial statements.				

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

(In thousands - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income	\$ 16,619	\$ (3,569)	\$ 32,828	\$ 20,717
Other comprehensive income (loss):				
Cash flow hedges	67	(144)	3,541	166
Less income tax benefit (expense)	(172)	56	(910)	(64)
Foreign currency translation adjustment	(1,037)	721	(3,241)	2,925
Less income tax (expense)	—	—	—	(252)
Total other comprehensive income (loss)	(1,142)	633	(610)	2,775
Total comprehensive income (loss)	\$ 15,477	\$ (2,936)	\$ 32,218	\$ 23,492

See condensed notes to consolidated financial statements.

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND
SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH
FLOWSFOR THE NINE MONTHS ENDED
SEPTEMBER 30, 2018 AND 2017

(In thousands - unaudited)

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	32,828	\$ 20,717
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	10,436	39,388
Gain on bargain purchase		(10,796)
Loss on sales and/or abandonment of property and equipment	425	219
Write-off of patents and intangible assets	44	86
Acquired in-process research and development	387	12,136
	(106)	(111)

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Amortization of deferred credits	
Amortization of long-term debt	514
issuance costs	
Deferred income taxes	(290)
Stock-based compensation expense	2,883
Changes in operating assets and liabilities, net of effects from acquisitions:	
Trade receivables	(10,963)
Other receivables	(449)
Inventory	(9,922)
Prepaid expenses and other current assets	(1,587)
Prepaid income taxes	(231)
Income tax refund receivables	280
Other assets	(2,992)
Trade payables	(876)
Accrued expenses	4,470
Income tax payable	(764)
Deferred compensation payable	1,107

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Other long-term obligations	574
Total adjustments	22,676
Net cash provided by operating activities	43,393
CASH FLOWS FROM INVESTING ACTIVITIES:	
Capital expenditures for:	
Property and equipment	(29,522)
Intangible assets	(1,927)
Proceeds from the sale of property and equipment	9
Issuance of note receivable	—
Cash paid in acquisitions, net of cash acquired	(103,500)
Net cash used in investing activities	(134,940)
See condensed notes to consolidated financial statements.	(continued)

Table of Contents**MERIT MEDICAL SYSTEMS, INC. AND
SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH
FLOWSFOR THE NINE MONTHS ENDED
SEPTEMBER 30, 2018 AND 2017

(In thousands - unaudited)

	Nine Months Ended September 30,		2017
	2018		
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of \$	213,276	\$	143,069
common stock			
Offering costs	(366)		(816)
Proceeds from issuance of	380,825		151,462
long-term debt			
Payments on	(450,575)		(197,962)
long-term debt			
Contingent payments related to	(184)		(45)
acquisitions			
Payment of taxes related to an	(2,616)		—
exchange of common stock			
Net cash provided by	140,360		95,708
financing activities			
NET OF EXCHANGE			30

RATES
ON
CASH

NET
INCREASE
IN

CASH 4,191

AND
CASH
EQUIVALENTS

CASH
AND
CASH
EQUIVALENTS:

Beginning
of 32,336
period 19,171

End
of \$ 51,955 \$ 23,362
period

SUPPLEMENTAL
DISCLOSURES
OF
CASH
FLOW
INFORMATION

Cash
paid
during
the
period
for:

Interest
(net
of
capitalized
interest
of \$ 8,018 \$ 5,953
\$468
and
\$371,
respectively)

Income
taxes \$ 6,069 \$ 4,029

SUPPLEMENTAL
DISCLOSURES
OF
NON-CASH
INVESTING
AND
FINANCING
ACTIVITIES

Property 3,058 \$ 1,394
and
equipment
purchases
in

accounts payable

Acquisition purchases in accrued expenses and other long-term obligations

Merit common stock surrendered

(43 and 0 shares, respectively) 2,262

\$ 12,000

\$ —

See condensed notes to consolidated financial statements.

(concluded)

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(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, 2018 and 2017 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, 2018 and December 31, 2017, and our results of operations and cash flows for the three and nine-month periods ended September 30, 2018 and 2017. The results of operations for the three and nine-month periods ended September 30, 2018 and 2017 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 (the "2017 Form 10-K") for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission (the "SEC") on March 1, 2018.

2. Inventories. Inventories at September 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	September 30,		December 31,	
	2018		2017	
Finished goods	\$	103,258	\$	86,555
Work-in-process		20,546		12,799
Raw materials		57,635		55,934
Total Inventories	\$	181,439	\$	155,288

3. Stock-Based Compensation Expense. Stock-based compensation expense before income tax expense for the three and nine months ended September 30, 2018 and 2017, consisted of the following (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Cost of sales	\$ 241	\$ 189	\$ 657	\$ 453
Research and development	141	110	412	262
Selling, general and administrative	1,291	893	3,425	2,168
Stock-based compensation expense before taxes	\$ 1,673	\$ 1,192	\$ 4,494	\$ 2,883

We recognize stock-based compensation expense (net of a forfeiture rate) for those awards which are expected to vest on a straight-line basis over the requisite service period. We estimate the forfeiture rate based on our historical experience and expectations about future forfeitures. As of September 30, 2018, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$20.7 million and is expected to be recognized over a weighted average period of 3.25 years.

During the three-month period ended September 30, 2018, we did not grant any new stock-based awards. During the nine-month period ended September 30, 2018, we granted stock-based awards representing 692,002 shares of our common stock. During the three and nine-month periods ended September 30, 2017, we granted stock-based awards representing 20,000 and approximately 1.3 million shares of our common stock, respectively. We use the Black-Scholes methodology to value the stock-based compensation expense for options. In applying the Black-Scholes methodology to the option grants, the fair value of our stock-based awards granted was estimated using the following assumptions for the periods indicated below:

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	Nine Months Ended September 30,	
	2018	2017
Risk-free interest rate	2.63%	1.77% - 1.83%
Expected option life	5.0 years	5.0 years
Expected dividend yield	—	—
Expected price volatility	34.06%	33.81% - 34.07%

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 options. We determine the expected term of the stock options using the historical exercise behavior of employees. The expected price volatility was 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. For options with a vesting period, compensation expense is recognized on a straight-line basis over the service period, which corresponds to the 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, 2018:						
Basic EPS	\$ 16,619	53,431	\$ 0.31	\$ 32,828	51,434	\$ 0.64
Effect of dilutive stock options and warrants		1,672			1,662	
Diluted EPS	\$ 16,619	55,103	\$ 0.30	\$ 32,828	53,096	\$ 0.62
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		667			462	
Period ended September 30, 2017:						
Basic EPS	\$ (3,569)	50,150	\$ (0.07)	\$ 20,717	48,332	\$ 0.43
		1,449			1,223	

Effect of
dilutive stock
options and
warrants

Diluted EPS	\$	(3,569)	51,599	\$	(0.07)	\$	20,717	49,555	\$	0.42
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Stock options
excluded from
the calculation
of common
stock
equivalents as
the impact was
anti-dilutive

200

434

5. Acquisitions. During July 2018, we purchased 1,786,000 preferred limited liability company units of Cagent Vascular, LLC, a medical device company ("Cagent"), for approximately \$2.2 million. Our investment has been accounted for as an equity investment reflected within other assets in the accompanying consolidated balance sheets because we are not able to exercise significant influence over the operations of Cagent. Our total investment in Cagent represents an ownership of approximately 19.5% of the outstanding limited liability company units.

On May 23, 2018, we entered into an asset purchase agreement with DirectACCESS Medical, LLC ("DirectACCESS") to acquire its assets, including, certain product distribution agreements for the FirstChoice™ Ultra High Pressure PTA Balloon Catheter. We accounted for this acquisition as a business combination. The purchase price for the assets was approximately \$7.3 million. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the DirectACCESS acquisition, which were included in selling, general and administrative expenses in our consolidated statements of income, were not material. The purchase price was preliminarily allocated as follows (in thousands):

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Inventories	\$	971
Intangibles		
Developed technology	4,840	
Customer list	120	
Trademarks	400	
Goodwill	938	
Total assets acquired	\$	7,269

We are amortizing the developed technology intangible asset over ten years, the related trademarks over ten years and the customer list on an accelerated basis over five years. The total weighted-average amortization period for these acquired intangible assets is approximately 9.9 years.

On May 18, 2018, we paid \$750,000 for a distribution agreement with QXMédical, LLC ("QXMédical") for the Q50® PLUS Stent Graft Balloon Catheter. We accounted for this acquisition as an asset purchase. We are amortizing the distribution agreement as an intangible asset over a period of ten years.

On April 6, 2018, we entered into long-term agreements with NinePoint Medical, Inc. ("NinePoint"), pursuant to which, we (a) became the exclusive worldwide distributor for the NvisionVLE® Imaging System with Real-time Targeting™ using Optical Coherence Tomography (OCT) and (b) acquired an option to purchase up to 100% of the outstanding equity in NinePoint throughout a three-month period commencing 18 months subsequent to the agreement date, both in exchange for total consideration of \$10.0 million. We accounted for this transaction as an asset purchase. The results of operations related to the distribution agreement have been included in our endoscopy operating segment since the acquisition date. During the three and nine months ended September 30, 2018, our net sales of NinePoint products were approximately \$1.4 million and \$2.5 million, respectively. We believe the NinePoint products will enhance the product offerings of our endoscopy operating segment and will be another step in our strategy to add therapy and disease-state products to our portfolio. The NinePoint products have 510(k) clearance in the United States, and NinePoint is preparing a CE mark application. We plan to launch the NinePoint products globally on a measured basis.

In addition, on April 6, 2018, we made a loan to NinePoint for \$10.5 million with a maturity date of April 6, 2023, at which time the loan, together with accrued interest thereon, will be due and payable. The loan bears interest at an annual rate of 9% and is collateralized by NinePoint's rights, interest and title to the NvisionVLE® Imaging System and substantially all other assets of NinePoint. This loan has been recorded as a note receivable within other long-term assets in our consolidated balance sheets.

On February 14, 2018, we acquired certain divested assets from Becton, Dickinson and Company ("BD"), for an aggregate purchase price of \$100.3 million. The assets acquired include the soft tissue core needle biopsy products sold under the tradenames of Achieve® Programmable Automatic Biopsy System, Temno® Biopsy System, Tru-Cut® Biopsy Needles as well as Aspira® Pleural Effusion Drainage Kits, and the Aspira® Peritoneal Drainage System. We accounted for this acquisition as a business combination.

During the three and nine-month periods ended September 30, 2018, our net sales of BD products were approximately \$11.8 million and \$30.3 million, respectively. It is not practical to separately report earnings related to the products acquired from BD, as we cannot split out sales costs related solely to the products we acquired from BD, principally because our sales representatives sell multiple products (including the products we acquired from BD) in our cardiovascular business segment. Acquisition-related costs associated with the BD acquisition, which are included in selling, general and administrative expenses in the accompanying consolidated statements of income, were

approximately \$1.8 million for the nine-month period ended September 30, 2018. The following table summarizes the purchase price allocated to the assets acquired from BD (in thousands):

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Inventories	\$	5,804
Property and equipment	748	
Intangibles		
Developed technology	74,000	
Customer list	4,200	
Trademarks	4,900	
Goodwill	10,613	
Total assets acquired	\$	100,265

We are amortizing the developed technology intangible assets over eight years, the related trademarks over nine years, and the customer lists on an accelerated basis over seven years. The total weighted-average amortization period for these acquired intangible assets is approximately eight years.

On October 2, 2017, we acquired a custom procedure pack business located in Melbourne, Australia from ITL Healthcare Pty Ltd. ("ITL"), for an aggregate purchase price of \$11.3 million. We accounted for this acquisition as a business combination. The following table summarizes the aggregate purchase price allocated to the assets acquired from ITL (in thousands):

Assets**Acquired**

Trade receivables	\$	1,287
Other receivables	56	
Inventories	1,808	
Prepaid expenses and other assets	65	
Property and equipment	1,053	
Intangibles		
Customer lists	5,940	
Goodwill	3,945	
Total assets acquired	14,154	

Liabilities**Assumed**

Trade payables	(216)
Accrued expenses	(747)
Deferred income tax liabilities	(1,901)
Total liabilities assumed	(2,864)

Total net assets acquired	\$	11,290
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We are amortizing the customer list on an accelerated basis over seven years. Acquisition-related costs associated with the ITL acquisition, which were included in selling, general and administrative expenses in the consolidated statements of income in the 2017 Form 10-K, were not material. The results of operations related to this acquisition have been included in our cardiovascular operating segment since the acquisition date. During the three and nine months ended September 30, 2018, our net sales of ITL products were approximately \$1.9 million and \$6.1 million, respectively. It is not practical to separately report the earnings related to the ITL acquisition, as we cannot split out sales costs related solely to the products we acquired from ITL, principally because our sales representatives sell multiple products (including the products we acquired from ITL) in our cardiovascular business segment.

On August 4, 2017, we acquired from Laurane Medical S.A.S. ("Laurane") and its shareholders inventories and the intellectual property rights associated with certain manual bone biopsy devices, manual bone marrow needles and muscle biopsy kits for an aggregate purchase price of \$16.5 million. We also recorded a contingent consideration liability of \$5.5 million related to royalties potentially payable to Laurane's shareholders pursuant to the terms of an intellectual property purchase agreement. We accounted for this acquisition as a business combination. The following table summarizes the aggregate purchase price (including contingent royalty payment liabilities) allocated to the assets acquired from Laurane (in thousands):

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Inventories	\$	594
Intangibles		
Developed technology	14,920	
Customer list	120	
Goodwill	6,366	
Total assets acquired	\$	22,000

We are amortizing the developed technology intangible asset over 12 years and the customer list on an accelerated basis over one year. The total weighted-average amortization period for these acquired intangible assets is 11.9 years. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the Laurane acquisition, which were included in selling, general and administrative expenses in the consolidated statements of income of our 2017 Form 10-K, were not material.

On July 3, 2017, we acquired from Osseon LLC ("Osseon") substantially all the assets related to Osseon's vertebral augmentation products. We accounted for this acquisition as a business combination. The purchase price for the assets was approximately \$6.8 million. Acquisition-related costs associated with the Osseon acquisition, which were included in selling, general and administrative expenses in the consolidated statements of income of our 2017 Form 10-K, 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 months ended September 30, 2018, our net sales of Osseon products were approximately \$478,000 and \$1.6 million, respectively. It is not practical to separately report the earnings related to the Osseon acquisition, as we cannot split out sales costs related solely to the products we acquired from Osseon, principally because our sales representatives sell multiple products (including the products we acquired from Osseon) in our cardiovascular business segment. The following table summarizes the purchase price allocated to the assets acquired (in thousands):

Inventories	\$	979
Property and equipment	58	
Intangibles		
Developed technology	5,400	
Customer list	200	
Goodwill	203	
Total assets acquired	\$	6,840

We are amortizing the developed technology intangible asset over nine years and customer lists on an accelerated basis over eight years. The total weighted-average amortization period for these acquired intangible assets is approximately 9.0 years.

On May 1, 2017, we entered into an agreement and plan of merger with Vascular Access Technologies, Inc. ("VAT"), pursuant to which we acquired the SAFECVAD™ device. We accounted for this acquisition as a business combination. The purchase price for the acquisition was \$5.0 million. We also recorded \$4.9 million of contingent consideration related to royalties potentially payable to VAT pursuant to the merger agreement. The following table summarizes the purchase price allocated to the net assets acquired (in thousands):

Intangibles

Developed technology	\$	7,800
In-process technology		920
Goodwill		4,281
Deferred tax liabilities	(3,101)	
Total net assets acquired	\$	9,900

We are amortizing the developed technology intangible asset over 15 years. The sales and results of operations related to the acquisition have been included in our cardiovascular segment since the acquisition date and were not material. Acquisition-related costs associated with the VAT acquisition, which were included in selling, general and administrative expenses in the consolidated statements of income of our 2017 Form 10-K, were not material.

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On January 31, 2017, we acquired the critical care division of Argon Medical Devices, Inc. ("Argon"), including a manufacturing facility in Singapore, the related commercial operations in Europe and Japan, and certain inventories and intellectual property rights within the United States. We made an initial payment of approximately \$10.9 million and received a subsequent reduction to the purchase price of approximately \$797,000 related to a working capital adjustment according to the terms of the purchase agreement. We accounted for the acquisition as a business combination.

Acquisition-related costs associated with the acquisition of the Argon critical care division during the year ended December 31, 2017, which were included in selling, general and administrative expenses in the consolidated statements of income of our 2017 Form 10-K, were approximately \$2.6 million. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the three and nine months ended September 30, 2018, our net sales of the Argon critical care products were approximately \$11.0 million and \$34.2 million, respectively. It is not practical to separately report the earnings related to the Argon critical care acquisition, as we cannot split out sales costs related solely to the products we acquired from Argon, principally because our sales representatives sell multiple products (including the products we acquired from Argon) in our cardiovascular business segment.

The assets and liabilities in the purchase price allocation for the Argon critical care acquisition are stated at fair value based on estimates of fair value using available information and making assumptions our management believes are reasonable. The following table summarizes the purchase price allocated to the net tangible and intangible assets acquired and liabilities assumed (in thousands):

**Assets
Acquired**

Cash and cash equivalents	1,436
Trade receivables	8,351
Inventories	1,022
Prepaid expenses and other assets	1,275
Income tax refund receivables	165
Property and equipment	2,319
Deferred income tax assets	202
Intangibles	
Developed technology	7,200
Customer lists	1,500
Trademarks	200

Total
assets
acquired

**Liabilities
Assumed**

Trade
payables

Accrued
expenses

Deferred
income
tax
liabilities

Total
liabilities
assumed

**Total
net
assets
acquired**

Gain
on
bargain
purchase
(1)

**Total
purchase
price** **10,100**

The total fair value of the net assets acquired from Argon exceeded the purchase price, resulting in a gain on bargain purchase which was recorded within other income (expense) in our consolidated statements of income. We believe the reason for the gain on bargain purchase was a result of the divestiture of a non-strategic, slow-growth critical care business for Argon. It is our

- (1) understanding that the divestiture allows Argon to focus on its higher growth interventional portfolio. A reduction of \$1.2 million was recorded since the bargain purchase gain was first presented in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, resulting from our ongoing activities, including reassessment of the assets acquired and liabilities assumed. The purchase price allocation for this acquisition is now final.

With respect to the Argon critical care assets, we are amortizing developed technology over seven years and customer lists on an accelerated basis over five years. While U.S. trademarks can be renewed indefinitely, we estimate that we will generate cash flow from the acquired trademarks for a period of five years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is approximately 6.0 years.

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On January 31, 2017, we acquired substantially all the assets, including intellectual property covered by approximately 40 patents and pending applications, and assumed certain liabilities, of Catheter Connections, Inc. (“Catheter Connections”), in exchange for payment of \$38.0 million. Catheter Connections, based in Salt Lake City, Utah, developed and marketed the DualCap® System, an innovative family of disinfecting products designed to protect patients from intravenous infections resulting from infusion therapy. We accounted for this acquisition as a business combination.

Acquisition-related costs associated with the Catheter Connections acquisition during the year ended December 31, 2017, which were included in selling, general and administrative expenses were approximately \$482,000. The results of operations related to this acquisition have been included in our cardiovascular operating segment since the acquisition date. During the three and nine months ended September 30, 2018, our net sales of the products acquired from Catheter Connections were approximately \$3.7 million and \$10.1 million, respectively. It is not practical to separately report the earnings related to the products acquired from Catheter Connections, as we cannot split out sales costs related solely to those products, principally because our sales representatives sell multiple products (including the DualCap System) in the cardiovascular business segment. The purchase price was allocated as follows (in thousands):

Assets	
Acquired	
Trade receivables	\$ 958
Inventories	2,157
Prepaid expenses and other assets	85
Property and equipment	1,472
Intangibles	
Developed technology	21,100
Customer lists	700
Trademarks	2,900
Goodwill	8,989
Total assets acquired	38,361
Liabilities	
Assumed	
Trade payables	(338)
Accrued expenses	(23)
Total liabilities assumed	(361)
Total net assets acquired	\$ 38,000

We are amortizing the Catheter Connections developed technology asset over 12 years, the related trademarks over ten years, and the associated customer list on an accelerated basis over eight years. We have estimated the weighted average life of the intangible Catheter Connections assets acquired to be approximately 11.7 years.

The following table summarizes our consolidated results of operations for the nine-month period ended September 30, 2017, as well as unaudited pro forma consolidated results of operations as though the acquisition of the Argon critical care division had occurred on January 1, 2016 (in thousands, except per common share amounts):

	Nine Months Ended	
	September 30, 2017	
	As Reported	Pro Forma
Net sales	\$ 536,955	\$ 539,715
Net income	20,717	10,039
Earnings per common share:		
Basic	\$ 0.43	\$ 0.21
Diluted	\$ 0.42	\$ 0.20

* The pro forma results for the three-month periods ended September 30, 2018 and 2017 and the nine-month period ended September 30, 2018 are not included in the table above because the operating results for the Argon critical care division acquisition were included in our consolidated statements of income for these periods.

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The unaudited pro forma information set forth above is for informational purposes only and includes adjustments related to the step-up of acquired inventories, amortization expense of acquired intangible assets, interest expense on long-term debt and changes in the timing of the recognition of the gain on bargain purchase. The pro forma information should not be considered indicative of actual results that would have been achieved if the acquisition of the Argon critical care division had occurred on January 1, 2016, or results that may be obtained in any future period. The pro forma consolidated results of operations do not include the acquisition of assets from BD because it was deemed impracticable to obtain information to determine net income associated with the acquired product lines which represent a small product line of a large, consolidated company without standalone financial information. The pro forma consolidated results of operations do not include the DirectACCESS, ITL, Laurane, Osseon, VAT or Catheter Connections acquisitions as we do not deem the pro forma effect of these transactions to be 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. The goodwill recognized from certain acquisitions is expected to be deductible for income tax purposes.

6. Revenue from Contracts with Customers.

We sell our medical products through a direct sales force in the U.S. and through OEM relationships, custom procedure tray manufacturers and a combination of direct sales force and independent distributors in international markets. Revenue is recognized when a customer obtains control of promised goods based on the consideration we expect to receive in exchange for these goods. This core principle is achieved through the following steps:

Identify the contract with the customer. A contract with a customer exists when (i) we enter into an enforceable contract with a customer that defines each party's rights regarding the goods to be transferred and identifies the payment terms related to these goods, (ii) the contract has commercial substance and, (iii) we determine that collection of substantially all consideration for services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. We do not have significant costs to obtain contracts with customers. For commissions on product sales, we have elected the practical expedient to expense the costs as incurred if the amortization period would have been one year or less.

Identify the performance obligations in the contract. Generally, our contracts with customers do not include multiple performance obligations to be completed over a period of time. Our performance obligations generally relate to delivering single-use medical products to a customer, subject to the shipping terms of the contract. Limited warranties are provided, under which we typically accept returns and provide either replacement parts or refunds. We do not have significant returns. We do not typically offer extended warranty or service plans.

Determine the transaction price. Payment by the customer is due under customary fixed payment terms, and we evaluate if collectability is reasonably assured. None of our contracts as of September 30, 2018 contained a significant financing component. Revenue is recorded at the net sales price, which includes estimates of variable consideration such as product returns, rebates, discounts, and other adjustments. The estimates of variable consideration are based on historical payment experience, historical and projected sales data, and current contract terms. Variable consideration is included in revenue only to the extent that it is probable that a significant reversal of the revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Allocate the transaction price to performance obligations in the contract. We typically do not have multiple performance obligations in our contracts with customers. As such, we recognize revenue upon transfer of the product to the customer's control at contractually stated pricing.

Recognize revenue when or as we satisfy a performance obligation. We satisfy performance obligations at a point in time upon either shipment or delivery of goods, in accordance with the terms of each contract with the customer. We do not have significant service revenue.

Disaggregation of Revenue

The disaggregation of revenue is based on type of product and geographical region. For descriptions of our product offerings and segments, see Note 12 in our 2017 Form 10-K.

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The following tables present revenue from contracts with customers for the three and nine-month periods ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30, 2018			Three Months Ended September 30, 2017		
	United States	International	Total	United States	International	Total
Cardiovascular						
Stand-alone devices	\$ 52,173	\$ 38,802	\$ 90,975	\$ 36,383	\$ 32,366	\$ 68,749
Custom kits and procedure trays	23,199	9,896	33,095	23,085	7,326	30,411
Inflation devices	7,819	15,074	22,893	8,241	11,792	20,033
Catheters	18,081	22,510	40,591	15,377	16,374	31,751
Embolization devices	5,145	7,250	12,395	5,414	6,838	12,252
CRM/EP	10,462	1,739	12,201	8,202	1,325	9,527
Total	116,879	95,271	212,150	96,702	76,021	172,723
Endoscopy						
Endoscopy devices	9,229	280	9,509	6,389	225	6,614
Total	\$ 126,108	\$ 95,551	\$ 221,659	\$ 103,091	\$ 76,246	\$ 179,337
	Nine Months Ended September 30, 2018			Nine Months Ended September 30, 2017		
	United States	International	Total	United States	International	Total
Cardiovascular						
Stand-alone devices	\$ 147,125	\$ 119,592	\$ 266,717	\$ 109,750	\$ 93,709	\$ 203,459
Custom kits and procedure trays	69,184	31,175	100,359	68,823	22,259	91,082
Inflation devices	23,647	45,970	69,617	24,257	35,072	59,329
Catheters	50,055	63,775	113,830	46,529	47,828	94,357
Embolization devices	15,272	22,434	37,706	16,548	20,388	36,936
CRM/EP	31,058	5,105	36,163	28,212	3,765	31,977
Total	336,341	288,051	624,392	294,119	223,021	517,140
Endoscopy						
Endoscopy devices	24,269	843	25,112	19,195	620	19,815
Total	\$ 360,610	\$ 288,894	\$ 649,504	\$ 313,314	\$ 223,641	\$ 536,955

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 and includes embolotherapeutic, cardiac rhythm management ("CRM"), electrophysiology ("EP"), critical care, and interventional oncology and spine devices. Our endoscopy segment focuses on the gastroenterology, pulmonary and thoracic surgery specialties, with a portfolio consisting primarily of stents, dilation balloons, certain inflation devices, guidewires, and other disposable products. 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, 2018 and 2017, are as follows (in thousands):

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	Three Months Ended September 30,			Nine Months Ended September 30,	
	2018	2017	2018	2017	
Net Sales					
Cardiovascular	\$ 212,150	\$ 172,723	\$ 624,392	\$ 517,140	
Endoscopy	9,509	6,614	25,112	19,815	
Total net sales	\$ 221,659	\$ 179,337	\$ 649,504	\$ 536,955	
Operating Income (Loss)					
Cardiovascular	\$ 18,199	\$ (1,207)	\$ 37,263	\$ 14,239	
Endoscopy	2,862	2,086	7,692	5,611	
Total operating income	\$ 21,061	\$ 879	\$ 44,955	\$ 19,850	

8. Recently Issued Financial Accounting Standards***Recently Adopted***

In October 2016, the Financial Accounting Standards Board (the "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 became effective for us as of January 1, 2018. The adoption of ASU 2016-16 did not have a material impact 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. We adopted ASU 2016-15 on January 1, 2018. The adoption of ASU 2016-15 did not have a material impact on our consolidated financial statements.

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. We adopted ASU 2016-01 on January 1, 2018. The adoption of ASU 2016-01 did not have a material impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. We adopted this ASU (and all subsequent ASUs that modified Topic 606) effective January 1, 2018 on a modified retrospective basis. Adoption of this standard did not result in significant changes to our accounting policies, business processes, systems or controls, or have a material impact on our financial position, results of operations or cash flows. As such, prior period amounts are not adjusted and continue to be reported under accounting standards then in effect, and we did not record a cumulative adjustment to the opening equity balance of retained earnings as of January 1, 2018. However, additional disclosures have been added in accordance with the requirements of Topic 606 and are reflected in Note 6.

Not Yet Adopted

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40)*. The new guidance reduces complexity for the accounting for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). ASU 2018-15 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. Implementation may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We are currently evaluating the anticipated impact of adopting ASU 2018-15 on our consolidated financial statements.

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In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)—Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies disclosure requirements related to fair value measurements. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard allows for early adoption of any removed or modified disclosures upon issuance of this ASU while delaying adoption of the additional disclosures until their effective date. We are currently evaluating the anticipated impact of adopting ASU 2018-13 on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for nonemployee share-based payment transactions by expanding the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Under the new standard, most of the guidance on stock compensation payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. This standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. While we continue to assess the potential impact of this standard, we do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, *Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from U.S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, which was enacted in December 2017 (the "2017 Tax Act"). ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. While we continue to assess our adoption policy for this standard, we do not expect adoption to have a material impact on our consolidated financial statements.

In August 2017, the FASB issued ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*, which expands and refines hedge accounting for both financial and non-financial risk components, aligns the recognition and presentation of the effects of hedging instruments and hedge items in the financial statements, and includes certain targeted improvements to ease the application of current guidance related to the assessment of hedge effectiveness. ASU 2017-12 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the anticipated impact of adopting ASU 2017-12 on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, 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 of ASU 2016-02 is permitted. In July 2018, the FASB issued ASU 2018-11 to provide a transition practical expedient by allowing entities to initially apply the new leases standard at the adoption date, recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, and not restate prior periods. We expect to adopt this as well as certain other practical expedients available to us under the new guidance. We have implemented processes and information technology tools to assist in our ongoing lease data collection and analysis. We are currently finalizing our lease portfolio analysis to determine the impact to our consolidated financial statements, and currently expect that most of our operating lease commitments will be recognized as lease liabilities and right-of-use assets upon our adoption of ASU 2016-02. We are updating our accounting policies and internal controls that will be impacted by the new guidance to ensure readiness for adoption in the first quarter of 2019.

We do not believe any other issued and not yet effective accounting standards will be relevant to our consolidated financial statements.

9. Income Taxes. On December 22, 2017, the 2017 Tax Act was signed into law. At December 31, 2017, we recorded a provisional net tax benefit related to the remeasurement of deferred taxes and a one-time tax expense for the transition tax. In accordance with SEC Staff Accounting Bulletin 118, income tax effects of the 2017 Tax Act may be refined upon obtaining, preparing, and/or analyzing additional information during the measurement period and such changes could be material. During the measurement period, provisional amounts may also be adjusted for the effects, if any, of interpretative guidance issued after December 31, 2017 by U.S. regulatory and standard-setting bodies. As of September 30, 2018, the amounts recorded for the 2017 Tax Act remain provisional and may be impacted by further analysis and subsequently issued guidance.

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For tax years beginning after December 31, 2017, the 2017 Tax Act introduces new provisions of U.S. taxation of certain Global Intangible Low-Taxed Income (“GILTI”). We have not yet determined our policy election with respect to whether to record deferred taxes for temporary basis differences expected to reverse as GILTI in future periods, or account for taxes on GILTI using the period cost method. We have, however, included an estimate of the current GILTI impact in our tax provision for the three and nine months ended September 30, 2018.

Our non-U.S. earnings are currently considered as indefinitely reinvested overseas. Previously, any repatriation by way of a dividend may have been subject to both U.S. federal and state income taxes, as adjusted for any non-U.S. tax credits. Under the 2017 Tax Act, such dividends should no longer be subject to U.S. federal tax. We are still analyzing how the 2017 Tax Act impacts our existing accounting position to indefinitely reinvest foreign earnings and have yet to determine whether we plan to change our position. We will record the tax effects of any change to our existing assertion in the period that we complete our analysis. If such earnings were to be distributed, any foreign withholding taxes could be material.

Our provision for income taxes for the three months ended September 30, 2018 and 2017 was a tax expense of approximately \$2.8 million and \$1.4 million, respectively, which resulted in an effective tax rate of 14.3% and (61.9)%, respectively. The change in the effective tax rate for the third quarter of 2018 compared to the third quarter of 2017 is primarily due to the discrete tax impact of the in-process research and development charge attributable to the IntelliMedical acquisition completed in the third quarter of 2017, which is not deductible for tax purposes.

Our provision for income taxes for the nine months ended September 30, 2018 and 2017 was a tax expense of approximately \$4.5 million and \$3.9 million, respectively, which resulted in an effective tax rate of 12.0% and 15.8%, respectively. The decrease in the effective income tax rate for the nine months ended September 30, 2018 compared to the corresponding period of 2017 was primarily due to a discrete tax benefit related to share-based payment awards.

10. Revolving Credit Facility and Long-Term Debt. Principal balances outstanding under our long-term debt obligations as of September 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
2016 Term loan	\$ 76,250	\$ 85,000
2016 Revolving credit loans	126,000	187,000
Collateralized debt facility	7,000	6,959
Less unamortized debt issuance costs	(383)	(487)
Total long-term debt	208,867	278,472
Less current portion	22,000	19,459
Long-term portion	\$ 186,867	\$ 259,013

2016 Term Loan and Revolving Credit Loans

On July 6, 2016, we entered into a Second Amended and Restated Credit Agreement (as amended to date, the “Second Amended Credit Agreement”), with Wells Fargo Bank, National Association, as administrative 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 our previously outstanding Amended and Restated Credit Agreement and all amendments thereto. The Second Amended Credit Agreement was amended on September 28, 2016 to allow for a new revolving credit loan to our wholly-owned subsidiary, on March 20, 2017 to allow flexibility in how we apply net proceeds received from equity issuances to prepay outstanding indebtedness, on December 13, 2017 to increase the revolving credit commitment by \$100 million up to \$375 million, and on March 28, 2018 to amend certain debt covenants.

The Second Amended Credit Agreement provides for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$375 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.

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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 also carries a commitment fee of 0.15% to 0.40% 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⁾	
January 1, 2018 and thereafter	3.5 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.

(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.

(4) Maximum level of the aggregate amount of all Facility Capital 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, 2018, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of September 30, 2018, we had outstanding borrowings of approximately \$202.3 million under the Second Amended Credit Agreement, with available borrowings of approximately \$248.4 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of September 30, 2018 was a fixed

rate of 2.87% on \$175.0 million as a result an interest rate swap (see Note 11) and a variable floating rate of 3.99% on \$27.3 million. Our interest rate as of December 31, 2017 was a fixed rate of 2.68% on \$175 million as a result of an interest rate swap and a variable floating rate of 2.82% on \$97 million.

Collateralized Debt Facility

On September 3, 2018, we renewed our loan agreement with HSBC Bank whereby HSBC Bank agreed to provide us with a loan in the amount of approximately \$7.0 million. The loan matures on January 10, 2019, with an extension available at our option, subject to certain conditions. The loan agreement bears interest at the six-month London Inter-Bank Offered Rate (“LIBOR”) plus 1.0%. The loan is secured by assets having a value not less than the currently outstanding loan balance. The loan contains covenants, representations and warranties and other terms customary for loans of this nature. As of September 30, 2018, our interest rate on the loan was a variable rate of 3.12%.

Future Payments

Future minimum principal payments on our long-term debt as of September 30, 2018, are as follows (in thousands):

Years Ending December 31	Future Minimum Principal Payments
Remaining 2018	\$ 3,750
2019	22,000
2020	17,500
2021	166,000
Total future minimum principal payments	\$ 209,250

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General. Our earnings and cash flows are subject to fluctuations due to changes in interest rates and foreign currency exchange rates, and we seek to mitigate a portion of these risks by entering into derivative contracts. The derivatives we use are interest rate swaps and foreign currency forward contracts. We recognize derivatives as either assets or liabilities at fair value in the accompanying consolidated balance sheets, regardless of whether or not hedge accounting is applied. We report cash flows arising from our hedging instruments consistent with the classification of cash flows from the underlying hedged items. Accordingly, cash flows associated with our derivative programs are classified as operating activities in the accompanying consolidated statements of cash flows.

We formally document, designate and assess the effectiveness of transactions that receive hedge accounting initially and on an ongoing basis. Changes in the fair value of derivatives that qualify for hedge accounting treatment are recorded, net of applicable taxes, in accumulated other comprehensive income (loss), a component of stockholders' equity in the accompanying consolidated balance sheets. For the ineffective portions of qualifying hedges, the change in fair value is recorded through earnings in the period of change. Changes in the fair value of derivatives not designated as hedging instruments are recorded in earnings throughout the term of the derivative.

Interest Rate Risk. 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 order 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 our Second Amended Credit Agreement that is solely due to changes in the benchmark interest rate.

Derivatives Designated as Cash Flow Hedges

On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap with a current notional amount of \$175.0 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 interest rate swap is scheduled to expire on July 6, 2021.

At September 30, 2018 and December 31, 2017, our interest rate swap qualified as a cash flow hedge. The fair value of our interest rate swap at September 30, 2018 was an asset of approximately \$8.3 million, which was partially offset by approximately \$2.1 million in deferred taxes. The fair value of our interest rate swap at December 31, 2017 was an asset of approximately \$5.7 million, which was offset by approximately \$1.5 million in deferred taxes.

Foreign Currency Risk. We operate on a global basis and are exposed to the risk that our financial condition, results of operations, and cash flows could be adversely affected by changes in foreign currency exchange rates. To reduce the potential effects of foreign currency exchange rate movements on net earnings, we enter into derivative financial instruments in the form of foreign currency exchange forward contracts with major financial institutions. Our policy is to enter into foreign currency derivative contracts with maturities of up to two years. We are primarily exposed to foreign currency exchange rate risk with respect to transactions and balances denominated in Euros, British Pounds, Chinese Renminbi, Mexican Pesos, Brazilian Reals, Australian Dollars, Hong Kong Dollars, Swiss Francs, Swedish Krona, Canadian Dollars, Danish Krone, Japanese Yen, Korean Won, and Singapore Dollars. We do not use derivative financial instruments for trading or speculative purposes. We are not subject to any credit risk contingent features related to our derivative contracts, and counterparty risk is managed by allocating derivative contracts among several major financial institutions.

Derivatives Designated as Cash Flow Hedges

For derivative instruments that are designated and qualify as cash flow hedges, the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income (loss) and reclassified into earnings in the same line item associated with the forecasted transaction and in the same period or periods during which the hedged transaction affects earnings. The remaining gain or loss on the derivative instrument in excess of the cumulative change in the present value of future cash flows of the hedged item, if any (i.e., the ineffective portion) or hedge components excluded from the assessment of effectiveness, are recognized in earnings during the current period. We enter into forward contracts on various foreign currencies to manage the risk associated with forecasted exchange rates which impact revenues, cost of sales, and operating

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expenses in various international markets. The objective of the hedges is to reduce the variability of cash flows associated with the forecasted purchase or sale of the associated foreign currencies.

We enter into approximately 150 cash flow foreign currency hedges every month. As of September 30, 2018, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with the following notional amounts (in thousands and in local currencies):

Currency	Symbol	Forward Notional Amount
Canadian Dollar	CAD	2,460
Swiss Franc	CHF	1,215
Chinese Renminbi	CNY	60,000
Danish Krone	DKK	10,835
Euro	EUR	12,270
British Pound	GBP	3,355
Japanese Yen	JPY	330,000
Mexican Peso	MXN	93,575
Swedish Krona	SEK	12,780

Derivatives Not Designated as Cash Flow Hedges

We forecast our net exposure in various receivables and payables to fluctuations in the value of various currencies, and we enter into foreign currency forward contracts to mitigate that exposure. We enter into approximately 20 foreign currency fair value hedges every month. As of September 30, 2018, we had entered into foreign currency forward contracts related to those balance sheet accounts, with the following notional amounts (in thousands and in local currencies):

Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	11,150
Brazilian Real	BRL	8,500
Canadian Dollar	CAD	3,098
Swiss Franc	CHF	255
Chinese Renminbi	CNY	95,228
Danish Krone	DKK	2,885
Euro	EUR	25,861
	GBP	1,584

British Pound		
Hong Kong Dollar	HKD	11,000
Japanese Yen	JPY	260,000
Korean Won	KRW	2,700,000
Mexican Peso	MXN	18,700
Swedish Krona	SEK	10,536
Singapore Dollar	SGD	6,900

Balance Sheet Presentation of Derivatives. As of September 30, 2018, and December 31, 2017, all derivatives, both those designated as hedging instruments and those that were not designated as hedging instruments, were recorded gross at fair value on our consolidated balance sheets. We are not subject to any master netting agreements.

The fair value of derivative instruments on a gross basis is as follows (in thousands):

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		Fair Value	
Balance Sheet Location		September 30, 2018	December 31, 2017
<i>Derivatives designated as hedging instruments</i>			
<i>Assets</i>			
Interest rate swap	Other assets (long-term)	\$ 8,284	\$ 5,749
Foreign currency forward contracts	Prepaid expenses and other assets	813	363
Foreign currency forward contracts	Other assets (long-term)	161	35
<i>Liabilities</i>			
Foreign currency forward contracts	Accrued expenses	(240)	(468)
Foreign currency forward contracts	Other long-term obligations	(56)	(82)
<i>Derivatives not designated as hedging instruments</i>			
<i>Assets</i>			
Foreign currency forward contracts	Prepaid expenses and other assets	\$ 360	\$ 223
<i>Liabilities</i>			
Foreign currency forward contracts	Accrued expenses	(475)	(841)

Income Statement Presentation of Derivatives.*Derivatives Designated as Cash Flow Hedges*

Derivative instruments designated as cash flow hedges had the following effects, before income taxes, on other comprehensive income and net earnings in our consolidated statements of income, consolidated statements of comprehensive income and consolidated balance sheets (in thousands):

Amount of Gain/(Loss) Recognized in OCI	Amount of Gain/(Loss) Reclassified from AOCI
Three Months Ended September 30,	Three Months Ended September 30,

2018	2017		2018	2017
<u>Derivative instrument</u>			<u>Location in statements of income</u>	
<i>Interest rate swaps</i>	664	\$ 1	<i>Interest Expense</i>	\$ 428 \$ 96
<i>Foreign currency forward contracts</i>	543	100	<i>Revenue</i>	86 (101)
			<i>Cost of sales</i>	26 250
Amount of Gain/(Loss) Recognized in OCI			Amount of Gain/(Loss) Reclassified from AOCI	
Nine Months Ended September 30,			Nine Months Ended September 30,	
2018	2017		2018	2017
<u>Derivative instrument</u>			<u>Location in statements of income</u>	
<i>Interest rate swaps</i>	3,532	\$ (611)	<i>Interest Expense</i>	\$ 998 \$ (8)
<i>Foreign currency forward contracts</i>	1,112	841	<i>Revenue</i>	(299) (141)
			<i>Cost of sales</i>	404 213

The net amount recognized in earnings during the three and nine months ended September 30, 2018 and 2017 due to ineffectiveness and amounts excluded from the assessment of hedge effectiveness were not significant.

As of September 30, 2018, approximately \$858,000, or \$637,000 after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in revenue and cost of sales over the succeeding twelve months. As of September 30, 2017, approximately \$2.6 million, or \$2.0 million after taxes, was expected to be reclassified from accumulated other comprehensive income to earnings in interest expense over the succeeding twelve months.

Derivatives Not Designated as Hedging Instruments

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The following gains/(losses) from these derivative instruments were recognized in our consolidated statements of income for the periods presented (in thousands):

Derivative Instrument	Location in statements of income	Three Months Ended September 30,			Nine Months Ended September 30,	
		2018	2017	2018	2017	
Foreign currency forward contracts	Other expense	\$ 1,143	\$ (1,459)	\$ 3,181	\$ (4,150)	

12. Fair Value Measurements. Our financial assets and (liabilities) carried at fair value measured on a recurring basis as of September 30, 2018 and December 31, 2017, consisted of the following (in thousands):

Description	Total Fair Value at September 30, 2018	Fair Value Measurements Using			Significant unobservable inputs (Level 3)
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)		
Interest rate contracts ⁽¹⁾	\$ 8,284	\$ —	\$ 8,284	\$ —	
Foreign currency contract assets, current and long-term ⁽²⁾	\$ 1,334	\$ —	\$ 1,334	\$ —	
Foreign currency contract liabilities, current and long-term ⁽³⁾	\$ (771)	\$ —	\$ (771)	\$ —	

Description	Total Fair Value at December 31, 2017	Fair Value Measurements Using			Significant unobservable inputs (Level 3)
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)		
Interest rate contracts ⁽¹⁾	\$ 5,749	\$ —	\$ 5,749	\$ —	
Foreign currency contract assets, current and long-term ⁽²⁾	\$ 621	\$ —	\$ 621	\$ —	
Foreign currency contract liabilities, current and long-term ⁽³⁾	\$ (1,391)	\$ —	\$ (1,391)	\$ —	

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- (1) The fair value of the interest rate contracts is determined using Level 2 fair value inputs and is recorded as other assets or other long-term obligations in the consolidated balance sheets.
- (2) The fair value of the foreign currency contract assets (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as prepaid expenses and other assets or other long-term assets in the consolidated balance sheets.
- (3) The fair value of the foreign currency contract liabilities (including those designated as hedging instruments and those not designated as hedging instruments) is determined using Level 2 fair value inputs and is recorded as accrued expenses or other long-term obligations 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 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, 2018 and 2017, consisted of the following (in thousands):

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	Three Months Ended September 30,			Nine Months Ended September 30,	
	2018	2017	2018	2017	
Beginning balance	\$ 10,912	\$ 5,572	\$ 10,956	\$ 683	
Contingent consideration liability recorded as the result of acquisitions (see Note 5)	—	5,500	—	10,400	
Fair value adjustments recorded to income during the period	(828)	20	(741)	39	
Contingent payments made	(53)	(15)	(184)	(45)	
Ending balance	\$ 10,031	\$ 11,077	\$ 10,031	\$ 11,077	

As of September 30, 2018, approximately \$9.8 million in contingent consideration liability was included in other long-term obligations and approximately \$280,000 was included in accrued expenses in our consolidated balance sheet. As of December 31, 2017, approximately \$10.7 million in contingent consideration liability was included in other long-term obligations and \$289,000 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 year ended December 31, 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 Level 3 inputs defined under authoritative guidance for fair value measurements, and we recorded a contingent receivable asset, which as of September 30, 2018 and December 31, 2017 had a value of approximately \$308,000 and \$760,000, respectively. 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 months ended September 30, 2018, we recorded a loss on the contingent receivable asset of approximately \$167,000 and \$299,000, respectively and received payments of approximately \$0 and \$153,000, respectively. As of September 30, 2018, the contingent receivable asset was included in other receivables as a current asset in our consolidated balance sheet. As of December 31, 2017, approximately \$319,000 was included in other long-term assets and approximately \$441,000 was included in other receivables as a current asset in our consolidated balance sheet.

The recurring Level 3 measurement of our contingent consideration liability and contingent receivable includes the following significant unobservable inputs at September 30, 2018 and December 31, 2017 (amounts in thousands):

Contingent consideration asset or liability	Fair Value at September 30, 2018	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$ 10,031	Discounted cash flow	Discount rate	9.9% - 15%

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contingent liability		Projected year of payments		2018-2037
Contingent receivable	\$ 308	Discounted cash flow	Discount rate	10%
asset			Weighted-average probability of milestone payment	35%
			Projected year of payments	2018-2019
Contingent consideration asset or liability	Fair Value at December 31, 2017	Valuation technique	Unobservable inputs	Range
Revenue-based payments	\$ 10,956	Discounted cash flow	Discount rate	9.9% - 15%
contingent liability			Probability of milestone payment	100%
			Projected year of payments	2018-2037
Contingent receivable	\$ 760	Discounted cash flow	Discount rate	10%
asset			Weighted-average probability of milestone payment	75%
			Projected year of payments	2018-2019

The contingent consideration liability and contingent receivable are 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

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most recent internal operational budgets and long-range strategic plans. 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. A decrease in the probability of any milestone payment may result in lower fair value measurements. Our determination of the fair value of the contingent consideration liability and contingent receivable 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 in our consolidated statements of income.

During the three and nine-month periods ended September 30, 2018, we had losses of approximately \$0 and \$86,000, respectively, compared to losses of approximately \$67,000 and \$86,000 for the three and nine-month periods ended September 30, 2017, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition (see Note 13).

We believe the carrying amount of cash and cash equivalents, receivables, and trade payables approximate fair value because of the immediate, short-term maturity of these financial instruments. Our long-term debt re-prices frequently due to variable rates and entails no significant changes in credit risk and, as a result, we believe the fair value of long-term debt approximates carrying value. 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.

13. Goodwill and Intangible Assets. The changes in the carrying amount of goodwill for the nine-month period ended September 30, 2018 were as follows (in thousands):

2018	
Goodwill balance at January 1	\$ 238,147
Effect of foreign exchange	(881)
Additions as the result of acquisitions	11,757
Goodwill balance at September 30	\$ 249,023

As of September 30, 2018, we had recorded \$8.3 million of accumulated goodwill impairment charges. All of the goodwill balance as of September 30, 2018 and December 31, 2017, is related to our cardiovascular segment.

Other intangible assets at September 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	September 30, 2018		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$ 18,676	\$ (4,665)	\$ 14,011
Distribution agreements	8,012	(5,509)	2,503
License agreements	24,913	(6,895)	18,018
Trademarks	21,514	(6,039)	15,475
	1,028	(993)	35

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Covenants not
to compete

Customer lists	35,590	(21,987)	13,603
In-process technology	920	—	920
Total	\$ 110,653	\$ (46,088)	\$ 64,565

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	December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents	\$ 16,528	\$ (3,737)	\$ 12,791
Distribution agreements	7,262	(4,686)	2,576
License agreements	23,783	(5,568)	18,215
Trademarks	16,224	(4,686)	11,538
Covenants not to compete	1,028	(968)	60
Customer lists	31,935	(18,482)	13,453
In-process technology	920	—	920
Total	\$ 97,680	\$ (38,127)	\$ 59,553

Aggregate amortization expense for the three and nine-month periods ended September 30, 2018 was approximately \$10.5 million and \$29.4 million, respectively. Aggregate amortization expense for the three and nine-month periods ended September 30, 2017 was approximately \$7.0 million and \$19.4 million, respectively.

We evaluate long-lived assets, including amortizing intangible assets, for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. We perform the impairment analysis at the asset group for which the lowest level of identifiable cash flows are largely independent of the cash flows of other assets and liabilities. During the three months ended September 30, 2018, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Quellent, LLC, all of which pertained to our cardiovascular segment, to the undiscounted cash flows expected to result from the asset group and determined that the carrying amount was not recoverable. We then determined the fair value of the amortizing assets related to the Quellent acquisition based on estimated future cash flows discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities. Some of the factors that influenced our estimated cash flows were slower than anticipated sales growth in the products acquired from our Quellent acquisition and uncertainty about future sales growth. The excess of the carrying value compared to the fair value was recognized as an intangible asset impairment charge. We recorded an impairment charge for Quellent of approximately \$657,000. We did not record any impairment charges during the three and nine months ended September 30, 2017.

Estimated amortization expense for the developed technology and other intangible assets for the next five years consists of the following as of September 30, 2018 (in thousands):

Year Ending December 31	
Remaining 2018	\$ 10,140
2019	39,647
2020	38,386
2021	31,025
2022	29,141

14. 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, contract disputes, and employment or other matters that are significant to our business. Based upon our

review of currently available information, we do not believe any such actions are likely to be, individually or in the aggregate, materially adverse to our business, financial condition, results of operations or liquidity.

In October 2016, we received a subpoena from the U.S. Department of Justice seeking information on certain of our marketing and promotional practices. We are in the process of responding to the subpoena, which we anticipate will continue during 2018. We have incurred, and anticipate that we will continue to incur, substantial costs in connection with the matter. The investigation is ongoing and at this stage we are unable to predict its scope, duration or outcome. Investigations such as this may result in the imposition of, among other things, significant damages, injunctions, fines or civil or criminal claims or penalties against our company or individuals. Legal expenses we incurred in responding to the U.S. Department of Justice subpoena for the three and nine-month periods ended September 30, 2018 were approximately \$946,000 and \$4.3 million, respectively.

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In the event of unexpected further developments, it is possible that the ultimate resolution of any of the foregoing matters, or other similar matters, if resolved in a manner unfavorable to us, 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.

15. Issuance of Common Stock. On July 30, 2018, we closed a public offering of 4,025,000 shares of common stock and received proceeds of approximately \$205.4 million, which is net of approximately \$12.0 million in underwriting discounts and commissions, and we paid approximately \$366,000 in other direct costs incurred in connection with this equity offering. The net proceeds from the offering were used primarily to repay outstanding borrowings (principally revolving credit loans) under our Second Amended Credit Agreement.

On March 28, 2017, we closed a public offering of 5,175,000 shares of common stock and received proceeds of approximately \$136.6 million, which is net of approximately \$8.8 million in underwriting discounts and commissions, and we paid approximately \$816,000 in other direct costs incurred in connection with this equity offering. The net proceeds from the offering were used primarily to repay outstanding borrowings (including our term loan and revolving credit loans) under our Second Amended Credit Agreement.

16. Subsequent Events. On October 1, 2018, we signed a definitive merger agreement (the "Cianna Merger Agreement") to acquire Cianna Medical, Inc. ("Cianna"). The transaction is subject to the satisfaction or waiver (in accordance with the provisions of the Cianna Merger Agreement) of certain closing conditions, including the approval of Cianna stockholders, clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. We anticipate that the transaction will close during the fourth quarter of 2018.

Subject to the terms and conditions of the Cianna Merger Agreement, we propose to pay up to \$200 million in connection with the acquisition of Cianna, as follows:

- \$135 million in cash at closing, subject to standard adjustments for working capital and other matters;
- an earn-out payment of \$15 million payable upon the achievement by Cianna of certain manufacturing capacity and manufacturing cost milestones on or before June 30, 2019; and
- earn-out payments of up to \$50 million in the aggregate, payable at the rate of 175% of the amount which annual net sales of Cianna products in each of 2019, 2020, 2021 and 2022 exceed annual net sales of Cianna products in the applicable preceding fiscal year.

Cianna claims to have developed the first non-radioactive, wire-free breast localization system. Its SCOUT® and SAVI® Brachy technologies are FDA-cleared and address what we believe are unmet needs in the delivery of radiation therapy, tumor localization and surgical guidance. We are currently evaluating the accounting treatment of the proposed transaction contemplated by the Cianna Merger Agreement.

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- expending significant resources for research, development, testing and regulatory approval or clearance of our products under development and any failure to develop the products, any failure of the products to be effective or any failure to obtain approvals for commercial use;
- violations of laws targeting fraud and abuse in the healthcare industry;
- risks relating to healthcare reform legislation negatively affecting our financial results, business, operations or financial condition;
- changes in the regulatory approval process and requirements in foreign countries, which could force us to incur additional expense or experience delays or uncertainties;
- loss of key personnel;
- product liability claims and recalls;
- failure to report adverse medical events to the FDA, which may subject us to sanctions that may materially harm our business;
- failure to maintain or establish sales capabilities on our own or through third parties, which may result in our inability to commercialize any of our products in countries where we lack direct sales and marketing capabilities;
- the addressable market for our product groups potentially being smaller than our estimates;
- demands for price concessions resulting from consolidations in the healthcare industry, group purchasing organizations, public procurement policies or other factors beyond our control;
- our inability to compete in markets, particularly if there is a significant change in relevant practices or technology;
- the effect of evolving U.S. and international laws and regulations regarding privacy and data protection;
- fluctuations in foreign currency exchange rates negatively impacting our financial results;
- termination or interruption of, or a failure to monitor, our supply relationships or increases in the price of our component parts, finished products, third-party services or raw materials, particularly petroleum-based products;
- our inability to accurately forecast customer demand for our products or manage our inventory;
- changes in international and national economic and industry conditions;
- inability to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations, including rapid increases in demand for our products;
- risks relating to our revenues being derived from a few products and medical procedures;
- risks relating to work stoppage, transportation interruptions, severe weather and natural disasters;
- fluctuations in our effective tax rate adversely affecting our business, financial condition or results of operations;
- limits on reimbursement imposed by governmental and other programs;
- failure to comply with applicable environmental laws and regulations;
- volatility of the market price of our common stock;
- dilution as a result of future equity offerings; and

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- other factors and risks referenced in our press releases and described or referenced in our reports and other documents filed with the Securities and Exchange Commission.

All 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. If we do update or correct one or more forward-looking statements, investors and others should not conclude that we will make additional updates or corrections. Additional factors that may have a direct bearing on our operating results are discussed in Part I, Item 1A “Risk Factors” in the 2017 Form 10-K.

Disclosure Regarding Trademarks

This report includes trademarks, tradenames and service marks that are our property or the property of other third parties. Solely for convenience, such trademarks and tradenames sometimes appear without any “™” or “®” symbol. However, failure to include such symbols is not intended to suggest, in any way, that we will not assert our rights or the rights of any applicable licensor, to these trademarks and tradenames.

OVERVIEW

The following discussion and analysis of our financial condition and results of operations 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 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 embolotherapeutic, cardiac rhythm management, electrophysiology, critical care and interventional oncology and spine devices. Our endoscopy segment focuses on the gastroenterology, pulmonary and thoracic surgery specialties, with a portfolio consisting primarily of stents, dilation balloons, certain inflation devices, guidewires, and other disposable products. Within those two operating segments, we offer products focused in five core product groups: peripheral intervention, cardiac intervention, interventional oncology and spine, cardiovascular and critical care and endoscopy.

For the three-month period ended September 30, 2018, we reported sales of approximately \$221.7 million, up approximately \$42.3 million or 23.6%, over sales from the three-month period ended September 30, 2017 of approximately \$179.3 million. For the nine-month period ended September 30, 2018, we reported sales of approximately \$649.5 million, up approximately \$112.5 million or 21.0%, over sales from the nine-month period ended September 30, 2017 of approximately \$537.0 million.

Gross profit as a percentage of sales increased to 46.0% for the three-month period ended September 30, 2018 as compared to 44.9% for the three-month period ended September 30, 2017. Gross profit as a percentage of sales decreased to 44.7% for the nine-month period ended September 30, 2018 as compared to 44.8% for the nine-month period ended September 30, 2017.

Net income for the three-month period ended September 30, 2018 was approximately \$16.6 million, or \$0.30 per diluted share, as compared to a net loss of \$(3.6) million, or \$(0.07) per diluted share, for the three-month period ended September 30, 2017. Net income for the nine-month period ended September 30, 2018 was approximately \$32.8 million, or \$0.62 per diluted share, as compared to \$20.7 million, or \$0.42 per diluted share, for the nine-month period ended September 30, 2017.

Recent Developments and Trends

In addition to the trends identified in the 2017 Form 10-K under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Overview,” and the impact of previously announced acquisitions, we believe that our business in 2018 will continue to be impacted by the following events and trends:

- On October 1, 2018, we signed the Cianna Merger Agreement, pursuant to which we propose to acquire Cianna. The proposed transaction has been approved by the boards of directors of both companies, and is subject to the satisfaction or waiver (in accordance with the provisions of the Cianna Merger Agreement) of certain closing conditions, including the approval of Cianna stockholders, clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions. We anticipate that the transaction will close during the fourth quarter of 2018.

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- We received FDA 510(k) clearance for a series of new tracheal/bronchial mini-stents which will be sold in our endoscopy operating segment. We also received 510(k) clearance for our EmboCube™ product line, which will be sold in our embolization devices product group in our cardiovascular operating segment.
- During 2018, a competitor experienced substantial global supply shortages due to internal issues, which has resulted in increased demand for our Merit Laureate® Hydrophilic Guide Wires, our offering of microcatheters (including the Merit Maestro®, SwiftNINJA® and the recently introduced Pursue™ Microcatheter), our Impress® Diagnostic Catheters and our vascular sheaths (including the recently introduced Prelude IDEal™ and PreludeEASE™ product offerings). We estimate that the impact of the increased demand for our products on our net sales for the three months ended September 30, 2018 was approximately \$4.0 million.

Additionally, we expect that (a) our net sales for the remainder of 2018 will be positively impacted by recently-awarded tenders, anticipated releases of new products and commencement of production of the Laurane product line in our Irish facility, and (b) our net income for the remainder of 2018 will be positively impacted by continued manufacturing efficiencies, cost-saving measures, and sales of our biopsy and drainage products, partially offset by several demand-based factors, including changes in our product mix, increases in revenue in certain markets served by distributors, and increases in labor costs and logistical expenses of addressing global supply requirements.

Table of Contents**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, 2018 and 2017, as indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net sales	100%	100%	100%	100%
Gross profit	46.0	44.9	44.7	44.8
Selling, general and administrative expenses	29.9	30.5	30.9	31.6
Research and development expenses	6.6	7.2	6.8	7.2
Intangible asset impairment charges	0.3	—	0.1	—
Contingent consideration expense (benefit)	(0.3)	—	(0.1)	—
Acquired in-process research and development expenses	—	6.7	0.1	2.3
Income from operations	9.5	0.5	6.9	3.7
Other income (expense) - net	(0.8)	(1.7)	(1.2)	0.9
Income (loss) before income taxes	8.7	(1.2)	5.7	4.6
Net income (loss)	7.5	(2.0)	5.1	3.9

Sales

Sales for the three-month period ended September 30, 2018 increased by 23.6%, or approximately \$42.3 million, compared to the corresponding period in 2017. Sales for the nine-month period ended September 30, 2018 increased by 21.0%, or approximately \$112.5 million, compared to the corresponding period in 2017. Listed below are the sales by product category within each of our two financial reporting segments for the three and nine-month periods ended September 30, 2018 and 2017 (in thousands, other than percentage changes):

	% Change	Three Months Ended September 30,		% Change	2018	Nine Months Ended September 30,	
		2018	2017			2018	2017
Cardiovascular							
Stand-alone devices	32.3%	\$ 90,975	\$ 68,749	31.1%	\$ 266,717	\$ 203,459	

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Custom kits and procedure trays	8.8%	33,095	30,411	10.2%	100,359	91,082
Inflation devices	14.3%	22,893	20,033	17.3%	69,617	59,329
Catheters	27.8%	40,591	31,751	20.6%	113,830	94,357
Embolization devices	1.2%	12,395	12,252	2.1%	37,706	36,936
CRM/EP	28.1%	12,201	9,527	13.1%	36,163	31,977
Total	22.8%	212,150	172,723	20.7%	624,392	517,140
Endoscopy						
Endoscopy devices	43.8%	9,509	6,614	26.7%	25,112	19,815
Total	23.6%	\$ 221,659	\$ 179,337	21.0%	\$ 649,504	\$ 536,955

Note: Certain revenue categories for 2017 have been adjusted from prior disclosure to reflect changes in product classifications to be consistent with updates in Merit's management of its product portfolios during 2018.

Cardiovascular Sales. Our cardiovascular sales for the three-month period ended September 30, 2018 were approximately \$212.2 million, up 22.8% when compared to the corresponding period for 2017 of approximately \$172.7 million. Sales for the three-month period ended September 30, 2018 were favorably affected by increased sales of (a) stand-alone devices (particularly our MAP™ Merit Angioplasty Packs, Prelude SYNC® Radial Compression Device, Medallion® Syringes, Merit Laureate® Hydrophilic Guide Wires, EN Snare® Endovascular Snare Systems, wires and tubing, as well as sales of products acquired in connection with our prior acquisitions, including the BD product lines and Catheter Connections) of approximately \$22.2 million, up 32.3% from the corresponding period for 2017; (b) catheters (particularly our Impress® Diagnostic Catheters, Prelude® and Prelude® Radial Sheath product lines, and our Merit Maestro® Microcatheters) of

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approximately \$8.8 million, up 27.8% from the corresponding period for 2017; (c) CRM/EP products (particularly our Heartspan® Transseptal Sheaths, Steerable Sheaths and Transseptal Needles) of approximately \$2.7 million, up 28.1% from the corresponding period for 2017; and (d) inflation devices (particularly our inflation kits sold through our OEM relationships) of approximately \$2.9 million, up 14.3% from the corresponding period for 2017.

Our cardiovascular sales for the nine-month period ended September 30, 2018 were approximately \$624.4 million, up 20.7%, when compared to the corresponding period for 2017 of approximately \$517.1 million. Sales for the nine-month period ended September 30, 2018 were favorably affected by increased sales of (a) our stand-alone devices (particularly our MAP™ Merit Angioplasty Packs, Prelude SYNC® Radial Compression Device, Merit Laureate® Hydrophilic Guide Wires, EN Snare® Endovascular Snare Systems, Medallion® Syringes, stopcocks, tubing and wires, as well as sales from products acquired in connection with our acquisitions, including the BD product lines, Argon critical care division, Catheter Connections, Osseon, and Laurane) of approximately \$63.3 million, up 31.1% from the corresponding period for 2017; (b) catheters (particularly our Impress® Diagnostic Catheters, ReSolve® Locking Drainage Catheters, Prelude® and Prelude® Radial Sheath product lines, and our Merit Maestro® Microcatheters) of approximately \$19.5 million, up 20.6% from the corresponding period for 2017; (c) custom kits and procedure trays (which includes sales from our acquisition of ITL) of approximately \$9.3 million, up 10.2% from the corresponding period for 2017; and (d) inflation devices (particularly our BASIXTouch™ and BasixCompak™ product lines, as well as our inflation kits sold through our OEM relationships) of approximately \$10.3 million, up 17.3% from the corresponding period for 2017.

Endoscopy Sales. Our endoscopy sales for the three-month period ended September 30, 2018 were approximately \$9.5 million, up 43.8%, when compared to sales in the corresponding period of 2017 of approximately \$6.6 million. Our endoscopy sales for the nine-month period ended September 30, 2018 were approximately \$25.1 million, up 26.7%, when compared to sales in the corresponding period of 2017 of approximately \$19.8 million. In each case, the increase was primarily related to an increase in sales of our EndoMAXX® fully covered esophageal stent, Elation® Balloon Dilator, the Aspira® Peritoneal Drainage System acquired from BD and products sold pursuant to our distribution agreement with NinePoint.

International Sales. International sales for the three-month period ended September 30, 2018 were approximately \$95.6 million, or 43.1% of net sales, up 25.3% when compared to the corresponding period in 2017. The increase in our international sales for the third quarter of 2018 compared to the third quarter of 2017 was primarily related to (a) sales increases in China of approximately \$3.9 million, or 20.8% when compared to the corresponding period in 2017, (b) sales increases in Japan of approximately \$4.9 million, or 61.7% when compared to the corresponding period in 2017, and (c) sales associated with our acquisition of certain product lines from BD.

International sales for the nine-month period ended September 30, 2018 were approximately \$288.9 million, or 44.5% of net sales, up 29.2% when compared to the nine-month period ended September 30, 2017. The increase in our international sales was primarily related to (a) sales increases in China of approximately \$16.5 million, or 29.8% when compared to the corresponding period in 2017, (b) sales increases in Japan of approximately \$8.7 million, or 34.0% when compared to the corresponding period in 2017, and (c) sales associated with our acquisition of certain product lines from BD.

Gross Profit

Our gross profit as a percentage of sales increased to 46.0% for the three-month period ended September 30, 2018, compared to 44.9% for the three-month period ended September 30, 2017. This increase was primarily related to changes in product mix including the addition of products acquired from BD with average margins of 80%, and increased efficiencies gained from our operations team.

Gross profit as a percentage of sales decreased to 44.7% for the nine-month period ended September 30, 2018, compared to 44.8% for the nine-month period ended September 30, 2017. This decrease was primarily due to integration costs associated with the BD acquisition and increased amortization as a result of acquisitions, which was partially offset by changes in product mix, including the addition of products acquired from BD with average margins of approximately 80%, and increased manufacturing efficiencies.

Operating Expenses

Selling, General and Administrative Expense. Selling, general and administrative ("SG&A") expenses increased approximately \$11.7 million, or 21.3%, for the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017. As a percentage of sales, SG&A expenses were 29.9% of sales for the three

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-month period ended September 30, 2018, compared to 30.5% for the three-month period ended September 30, 2017. SG&A expenses increased approximately \$30.5 million, or 17.9%, for the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017. As a percentage of sales, SG&A expenses decreased to 30.9% of sales for the nine-month period ended September 30, 2018, compared to 31.6% of sales for the nine-month period ended September 30, 2017. The increase in SG&A expense was primarily related to acquisition and integration costs for our acquisition of BD, increased headcount and increased amortization as a result of acquisitions, which was partially offset by a reduction in legal expenses incurred in responding to the pending subpoena from the Department of Justice when compared to SG&A expenses in the corresponding periods of 2017.

Research and Development Expenses. Research and development ("R&D") expenses for the three-month period ended September 30, 2018 were approximately \$14.5 million, up 13.1%, when compared to R&D expenses in the corresponding period of 2017 of approximately \$12.8 million. R&D expenses for the nine-month period ended September 30, 2018 were approximately \$44.2 million, up 14.2%, when compared to R&D expenses in the corresponding period of 2017 of approximately \$38.7 million. The increase in R&D expenses was largely due to hiring additional research and development personnel to support various new core and acquired product developments.

Operating Income

The following table sets forth our operating income by financial reporting segment for the three and nine-month periods ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Income (Loss)				
Cardiovascular	\$ 18,199	\$ (1,207)	\$ 37,263	\$ 14,239
Endoscopy	2,862	2,086	7,692	5,611
Total operating income	\$ 21,061	\$ 879	\$ 44,955	\$ 19,850

Cardiovascular Operating Income. Our cardiovascular operating income for the three-month period ended September 30, 2018 was approximately \$18.2 million, compared to an operating loss of approximately \$(1.2) million for the three-month period ended September 30, 2017. Our cardiovascular operating income for the nine-month period ended September 30, 2018 was approximately \$37.3 million, compared to operating income of approximately \$14.2 million for the nine-month period ended September 30, 2017. The increase in cardiovascular operating income was primarily related to the acquired in-process research and development charge recorded in the third quarter of 2017, which did not repeat in the third quarter of 2018, and increased sales and improved gross margins in the third quarter of 2018, which were partially offset by increased headcount, increased amortization as a result of acquisitions, and expenses associated with foreign market expansion.

Endoscopy Operating Income. Our endoscopy operating income for the three-month period ended September 30, 2018 was approximately \$2.9 million, compared to approximately \$2.1 million for the three-month period ended September 30, 2017. Our endoscopy operating income for the nine-month period ended September 30, 2018 was approximately \$7.7 million, compared to approximately \$5.6 million for the nine-month period ended September 30, 2017. The increase for the three and nine months ended September 30, 2018 compared to the same periods of 2017, was primarily the result of higher sales (principally related to sales of the NinePoint products of approximately \$1.4 million and \$2.5 million, during the three and nine months ended September 30, 2018, respectively) and lower SG&A expenses as a percentage of sales.

Effective Tax Rate

Our effective income tax rate for the three-month periods ended September 30, 2018 and 2017 was 14.3%, and (61.9)%, respectively. The change in the effective tax rate for the third quarter of 2018 compared to the third quarter of 2017 is primarily due to the discrete tax impact of the in-process research and development charge attributable to the IntelliMedical acquisition completed in the third quarter of 2017, which was not deductible for tax purposes.

Our effective income tax rate for the nine-month periods ended September 30, 2018 and 2017 was 12.0% and 15.8%, respectively. The decrease in the effective income tax rate was primarily due to a discrete tax benefit related to share-based payment awards.

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Other Income (Expense)

Our other income (expense) for the three-month periods ended September 30, 2018 and 2017 was approximately \$(1.7) million, and \$(3.1) million, respectively. rily a result of the bargain purchase gain related to the acquisition of the Argon critical care division which was adjusted during the third quarter of 2017 and fluctuations in the currency gains and losses during the third quarter of 2018.

Our other income (expense) for the nine-month periods ended September 30, 2018 and 2017 was approximately \$(7.6) million, and \$4.8 million, respectively. The change in other income (expense) for these periods was primarily a result of the bargain purchase gain related to the acquisition of the Argon critical care division the first quarter of 2017, which did not recur in 2018, and increased interest expense in 2018 due to higher average debt balances used to finance the BD and other acquisitions.

Net Income

Our net income for three-month periods ended September 30, 2018 and 2017 was approximately \$16.6 million and \$(3.6) million, respectively. The increase in net income was primarily due to increased sales and improvement in our gross margin. In addition, the net loss for the three months ended September 30, 2017 was primarily due to the acquired in-process research and development expenses of \$12.1 million primarily attributable to the IntelliMedical acquisition, which did not recur in 2018.

Our net income for nine-month periods ended September 30, 2018 and 2017 was approximately \$32.8 million and \$20.7 million, respectively. The increase in net income was primarily related to increased sales, lower SG&A expenses as a percentage of sales and the acquired in-process research and development expenses of \$12.1 million in 2017 attributable to the IntelliMedical acquisition, which did not recur in 2018, partially offset by the gain on bargain purchase in 2017 of approximately \$10.8 million related to the acquisition of the Argon critical care division.

Table of Contents**LIQUIDITY AND CAPITAL RESOURCES****Capital Commitments, Contractual Obligations and Cash Flows**

At September 30, 2018 and December 31, 2017, we had cash and cash equivalents of approximately \$52.0 million and \$32.3 million respectively, of which approximately \$46.9 million and \$30.4 million, respectively, were held by foreign subsidiaries. The 2017 Tax Act one-time repatriation tax liability effectively taxes the undistributed earnings previously deferred from U.S. income taxes. We have not provided for foreign withholding tax on the undistributed earnings from our non-U.S. subsidiaries because such earnings are currently considered to be indefinitely reinvested. We are still analyzing how the 2017 Tax Act impacts our existing accounting position to indefinitely reinvest foreign earnings and have yet to determine whether we plan to change our position. The cash held by our foreign subsidiaries for indefinite reinvestment is used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations.

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, 2018 and December 31, 2017, we had cash and cash equivalents of approximately \$21.0 million and \$13.1 million, respectively, held by our subsidiary in China.

Cash flows provided by operating activities. Cash provided by operating activities during the nine-month periods ended September 30, 2018 and 2017 was primarily the result of net income excluding non-cash items, offset by shifts in working capital. Our working capital as of September 30, 2018 and December 31, 2017 was approximately \$247.8 million and \$200.5 million, respectively. The increase in working capital as of September 30, 2018 compared to December 31, 2017 was primarily the result of increases in trade receivables and inventories which were partially offset by an increase in trade payables and accrued expenses. As of September 30, 2018 and December 31, 2017, we had a current ratio of 2.77 to 1 and 2.73 to 1, respectively.

During the nine-month period ended September 30, 2018, our inventory balance increased approximately \$26.2 million, from approximately \$155.3 million as of December 31, 2017 to approximately \$181.4 million as of September 30, 2018. The increase in the inventory balance was due to several factors, including acquisitions and expansion to support increased sales and the opening of new modified direct sales markets. The trailing twelve-month inventory turns as of September 30, 2018 was 2.84, compared to 2.91 for the twelve-month period ended December 31, 2017.

Cash flows provided by financing activities. Cash provided by financing activities for the nine-month period ended September 30, 2018 was approximately \$140.4 million compared to approximately \$95.7 million for the nine-month period ended September 30, 2017, an increase of approximately \$44.7 million. The increase in net cash provided from financing activities was primarily the result of higher proceeds from the issuance of common stock in 2018 (compared to the proceeds we received from issuance of common stock in 2017), partially offset by higher net debt repayments in 2018.

On September 3, 2018, we renewed our loan agreement with HSBC Bank whereby HSBC Bank agreed to provide us with a loan in the amount of approximately \$7.0 million. The loan matures on January 10, 2019, with an extension available at our option, subject to certain conditions. The loan agreement bears interest at the six-month LIBOR rate, plus 1.0%. The loan is secured by assets having a value not less than the currently outstanding loan balance. The loan contains covenants, representations and warranties and other terms customary for loans of this nature. As of September 30, 2018, our interest rate on the loan was a variable rate of 3.12%.

The Second Amended Credit Agreement provides for a term loan of \$150 million and a revolving credit commitment up to an aggregate amount of \$375 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) 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 0.40% per annum on the unused portion.

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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⁾	
January 1, 2018 and thereafter	3.5 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.

(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.

(4) Maximum level of the aggregate amount of all Facility Capital 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, 2018, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of September 30, 2018, we had outstanding borrowings of approximately \$202.3 million under the Second Amended Credit Agreement (a decrease in outstanding borrowings under the Second Amended Credit Agreement of approximately \$69.8 million from December 31, 2017, which was principally due to applying the proceeds of the July 2018 common stock offering toward our outstanding debt balance in the third quarter of 2018, partially offset by increased debt levels in the first six months of 2018 to fund acquisitions) with available borrowings of approximately \$248.4 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of September 30, 2018 was a fixed rate of 2.87% on \$175.0 million as a result of an interest rate swap (see Note 11 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report) and a variable floating rate of 3.99% on \$27.3 million. Our interest rate as of December 31, 2017 was a fixed rate of 2.68% on \$175.0 million as a result of an interest rate swap and a variable floating rate of 2.82% on \$97.0 million.

As discussed in Note 15 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report, the net proceeds from our offering of common stock, which closed on July 30, 2018, were used primarily to repay outstanding borrowings (primarily revolving credit loans) under the Second Amended Credit Agreement.

Cash flows used in investing activities. Our cash flows used in investing activities for the nine-month period ended September 30, 2018 was approximately \$182.8 million compared to approximately \$134.9 million for the nine-month period ended September 30, 2017, an increase of approximately \$47.8 million. This increase was primarily a result of an increase of approximately \$19.3 million in net cash paid for acquisitions during the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017 (see Note 5 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report), combined with a \$17.5 million increase in capital expenditures for property and equipment. Capital expenditures for property and equipment were approximately \$47.0 million and \$29.5 million for the nine-month periods ended September 30, 2018 and 2017, respectively.

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

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Off-Balance Sheet Arrangements

Under SEC regulations, we are required to disclose our off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, such as changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors. As of September 30, 2018, we have no off-balance sheet arrangements.

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:

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, 2017, 2016 and 2015, we recorded obsolescence expense of approximately \$6.1 million, \$3.9 million and \$2.8 million, respectively, and wrote off approximately \$2.9 million, \$2.8 million and \$2.5 million, respectively. Based on this historical trend, we believe that our inventory balances as of September 30, 2018 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. and international distributors.

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 that 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. Additionally, changes in tax law - such as the 2017 Tax Act - may be subject to evolving interpretation over a period of time

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following their enactment. Such differences and evolving interpretations 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 allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. 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 guideline public company market-based approach and a discounted cash flow income-based approach. 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 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 2018, which was completed during the third quarter of 2018, 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 subject to amortization 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. In-process technology intangible assets, which are not subject to amortization until projects reach commercialization, are assessed for impairment at least annually and more frequently if events occur that would indicate a potential reduction in the fair value of the assets below their carrying value. During the third quarter of 2018, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Quellent, LLC to the undiscounted cash flows expected to result from the asset group and determined that the carrying amount was not recoverable. We then determined the fair value of the amortizing assets related to the Quellent acquisition based on estimated future cash flows discounted back to their present value using a discount rate that reflects the risk profiles of the underlying activities. Some of the factors that influenced our estimated cash flows were slower than anticipated sales growth in the products acquired from our Quellent acquisition and uncertainty about future sales growth. The excess of the carrying value compared to the fair value was recognized as an intangible asset impairment charge. We recorded an impairment charge for Quellent of approximately \$657,000 during the third quarter of 2018.

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 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.

Table of Contents**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK****Currency Risk**

Our principal market risk relates to changes in the value of the following currencies relative to the U.S. Dollar (USD):

- Euro (EUR)
- Chinese Yuan Renminbi (CNY), and
- British Pound (GBP).

We also have a limited market risk relating to the following currencies (among others):

- Hong Kong Dollar (HKD),
- Mexican Peso (MXN),
- Australian Dollar (AUD),
- Canadian Dollar (CAD),
- Brazilian Real (BRL),
- Swiss Franc (CHF),
- Swedish Krona (SEK),
- Danish Krone (DKK),
- Singapore Dollars (SGD),
- South Korean Won (KRW), and
- Japanese Yen (JPY).

Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. For the nine-month period ended September 30, 2018, a portion of our net sales (approximately \$213.8 million, representing approximately 32.9% of our aggregate net sales), 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, generally have a positive effect on our operating income. As we continue to expand our operations in China, we have been increasingly exposed to currency risk related to our CNY-denominated revenue. In general, a strengthening of the U.S. Dollar against CNY has a negative effect on our operating income. The following table presents the USD impact to reported operating income related to a hypothetical positive and negative 10% exchange rate fluctuation in the value of the U.S. Dollar relative to both the EUR and CNY (annual amounts):

(in
thousands)

	USD Relative to Other Currency	
	10% Strengthening	10% Weakening
Impact to Operating Income of:		
EUR	\$3,400	\$(3,400)
CNY	\$(6,200)	\$6,200

During the three and nine months ended September 30, 2018, exchange rate fluctuations of foreign currencies against the U.S. Dollar had the following impact on sales, cost of sales and gross profit (in thousands, except basis points):

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Three Months Ended September 30, 2018		Nine Months Ended September 30, 2018	
Currency Impact to Reported Amounts		Currency Impact to Reported Amounts	
Percent Increase/(Decrease) Increase/(Decrease)	Increase/(Decrease)	Percent Increase/(Decrease)	Increase/(Decrease)
Net Sales \$(10,689%)	\$7,380	1.1%	
Cost of Sales \$(838%)	\$5,434	1.5%	
Gross Profit \$(1,216%) (1)	\$1,945	0.7%	

(1) Represents approximately 72 basis points decrease and 21 basis points decrease in gross margin percentage for the three and nine months ended September 30, 2018, respectively.

The impact to sales for the three months ended September 30, 2018 was primarily a result of unfavorable impacts due to sales denominated in CNY and BRL. The impact to cost of sales was primarily a result of unfavorable impacts from EUR fluctuations related to manufacturing costs from our facilities in Europe denominated in EUR and favorable MXN fluctuations on our manufacturing costs from our facility in Tijuana, Mexico denominated in MXN.

We forecast our net exposure related to sales and expenses denominated in foreign currencies. As of September 30, 2018, we had entered into foreign currency forward contracts, which qualified as cash flow hedges, with the following notional amounts (in thousands and in local currencies):

Currency	Symbol	Forward Notional Amount
Canadian Dollar	CAD	2,460
Swiss Franc	CHF	1,215
Chinese Renminbi	CNY	60,000
Danish Krone	DKK	10,835
Euro	EUR	12,270
British Pound	GBP	3,355
Japanese Yen	JPY	330,000
Mexican Peso	MXN	93,575
Swedish Krona	SEK	12,780

We also forecast our net exposure in various receivables and payables to fluctuations in the value of various currencies, and we enter into foreign currency forward contracts to mitigate that exposure. As of September 30, 2018, we had entered into the following foreign currency forward contracts (which were not designated as hedging instruments) related to those balance sheet accounts (amounts in thousands and in local currencies):

Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	11,150
Brazilian Real	BRL	8,500
Canadian Dollar	CAD	3,098
Swiss Franc	CHF	255
Chinese Renminbi	CNY	95,228
Danish Krone	DKK	2,885
Euro	EUR	25,861
British Pound	GBP	1,584
Hong Kong Dollar	HKD	11,000
Japanese Yen	JPY	260,000
Korean Won	KRW	2,700,000
Mexican Peso	MXN	18,700
Swedish Krona	SEK	10,536
Singapore Dollar	SGD	6,900

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See Note 11 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report for a discussion of our foreign currency forward contracts.

Interest Rate Risk. As discussed in Note 10 to our condensed consolidated financial statements, as of September 30, 2018, we had outstanding borrowings of approximately \$202.3 million under the Second Amended Credit Agreement, a decrease in outstanding borrowings under the Second Amended Credit Agreement of approximately \$69.8 million from December 31, 2017, which was principally due to applying the proceeds of the July 2018 common stock offering toward our outstanding debt balance in the third quarter of 2018, partially offset by increased debt levels in the first six months of 2018, primarily to fund acquisitions. Accordingly, our earnings and after-tax cash flow are increasingly affected by changes in interest rates. On August 5, 2016, we entered into a pay-fixed, receive-variable interest rate swap with Wells Fargo, which as of September 30, 2018 had a notional amount of \$175 million, to fix the one-month LIBOR rate at 1.12%. The interest rate swap is scheduled to expire on July 6, 2021. This instrument is intended to reduce our exposure to interest rate fluctuations and was 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 \$0.3 million annually for each one percentage point change in the average interest rate under these borrowings.

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 is responsible for establishing and maintaining adequate disclosure controls and procedures for our company. Consequently, 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 Exchange Act as of September 30, 2018. 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

During the quarter ended September 30, 2018, 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).

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 14 “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 the 2017 Form 10-K, as well as the amended and updated risk factors included below (which replace equivalent risk factors disclosed in Part I, Item 1A. "Risk Factors" of the 2017 Form 10-K). Such risk factors could materially affect our business, financial condition or future results.

The risks described in our 2017 Form 10-K and in the amended and updated risk factors below 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.

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

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

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

On October 1, 2018, we entered into the Cianna Merger Agreement, pursuant to which we propose to acquire Cianna. Completion of the proposed transaction is subject to customary closing conditions, including, among others, (i) obtaining antitrust approvals in the United States, (ii) subject to certain exceptions, the accuracy of the representations and warranties of the parties, and (iii) material compliance by the parties with their pre-closing obligations under the Cianna Merger Agreement. In addition to risks and uncertainties generally associated with our acquisition strategy, some of which are identified in the preceding paragraphs, the proposed Cianna acquisition presents risks and uncertainties which are unique to that transaction, including the possibility that conditions to the closing of the

proposed transaction, including regulatory conditions, will not be satisfied; our potential inability to successfully manage the proposed transaction, integrate the acquired operations and achieve projected financial results, product development and other anticipated benefits of the proposed acquisition; uncertainties as to whether we will achieve sales, gross margin, cost of goods sold, cash flow and other results from the proposed transaction which are consistent with Cianna's business and operations; unknown costs and risks associated with the business and operations of Cianna; and inherent risks and uncertainties relating to our internal models and projections.

We have incurred, and will likely continue to incur, significant expenses in connection with negotiating and consummating various acquisition and other strategic transactions, and we may inherit significant liabilities in connection with prospective acquisitions or other strategic transactions, including regulatory, infringement, product liability, discrimination or other legal

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claims or issues. In addition, we may not realize competitive advantages, synergies or other benefits anticipated in connection with any such acquisition or other transaction. If we do not adequately identify targets for, or manage issues related to, our future acquisitions and similar transactions, such transactions may have an adverse effect on our business, operations or financial condition.

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

The marketing clearances and approvals from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific uses. We are prohibited from marketing or promoting any uncleared or unapproved use of our product. However, physicians may use these products in ways or circumstances other than those strictly within the scope of the regulatory approval or clearance. The use of our products for unauthorized purposes could arise from our sales personnel or distributors violating our policies by providing information or recommendations about such unauthorized uses. Consequently, claims may be asserted by the FDA or other enforcement agencies that we are not in compliance with applicable laws or regulations or have improperly promoted our products for uncleared or unapproved uses. The FDA or such other agencies could require a recall of products or allege that our promotional activities misbrand or adulterate our products or violate other legal requirements, which could result in investigations, prosecutions, fines or other civil or criminal actions.

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

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

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

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

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission or a PMA supplement in the first instance, but the FDA may review the manufacturer's decisions not to seek a new 510(k)

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

There is no assurance that we will be able to obtain the necessary regulatory clearances or approvals for any product on a timely basis or at all. Further, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing

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regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Delays in receipt of, or failure to obtain, regulatory clearances for any product enhancements or new products we develop would result in delayed or no realization of revenue from such product enhancements or new products and in substantial additional costs, which could decrease our profitability.

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

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

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

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

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

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

Our forecasts of customer demand and related decisions that we make about production levels may not take into account potential opportunities created by regulatory issues, supply disruptions or other challenges experienced by our competitors. We generally do not know the extent and cannot predict the duration of these challenges experienced by our competitors. As a result, our estimates about related increased demand for our products are inherently uncertain and subject to change. If our estimates incorrectly forecast the extent or duration of this increased demand, or the product types to which it relates, our revenues, margins and earnings could be adversely affected.

Table of Contents**ITEM 6. EXHIBITS**

The following exhibits required by Item 601 of Regulation S-K are filed herewith or have been filed previously with the SEC as indicated below:

Exhibit No.	Description
3.1	<u>Second Amended and Restated Articles of Incorporation (1)</u>
3.2	<u>Third Amended and Restated Bylaws (1)</u>
10.1	<u>Merit Medical Systems, Inc. 2018 Long-Term Incentive Plan (2)</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.Def	Definition Linkbase Document
101.Pre	

	Presentation
	Linkbase
	Document
	Labels
101.Lab	Linkbase
	Document
	Calculation
101.Cal	Linkbase
	Document
	Schema
101.Sch	Document
	Instance Document
	- the instance
	document does not
	appear in the
101.Ins	Interactive Data
	File because its
	XBRL tags are
	embedded within
	the Inline XBRL
	document

1. Incorporated by reference from our Current Report on Form 8-K filed on May 31, 2018 (as amended).
2. Incorporated by reference from our Form S-8 filed on June 4, 2018.

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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, 2018

By: /s/ FRED P.
LAMPROPOULOS

Fred P.
Lampropoulos,
President and
Chief Executive
Officer

Date:
November 9, 2018

By: /s/ RAUL PARRA

Raul Parra
Chief Financial
Officer and
Treasurer