MERIT MEDICAL SYSTEMS INC

Form 10-Q August 09, 2018 Table of Contents

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 $^{\rm x}$ 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm o}_{1934}$

FOR THE TRANSITION PERIOD FROM TO.

Commission File Number 0-18592

MERIT MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Utah 87-0447695

(State or other jurisdiction of incorporation or organization) (IRS Employer Identification No.)

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

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 Accelerated Non-Accelerated Filer o (Do not check if a Smaller Reporting Emerging Growth Filer x Filer o smaller reporting company) Company o Company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

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

Common Stock 54,735,486

Title or class

Number of Shares

Outstanding at August 6, 2018

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
JUNE 30, 2018 AND DECEMBER 31, 2017
(In thousands)

ASSETS	June 30, 2018 (unaudited)	December 31, 2017
CURRENT ASSETS:	* 10.710	***
Cash and cash equivalents Trade receivables — not of alloweness for uncellectible accounts — 2018 — \$1,021 and 20	\$43,512	\$32,336
Trade receivables — net of allowance for uncollectible accounts — 2018 — \$1,921 and 20 \$1,769	131,943	105,536
Other receivables	8,490	9,429
Inventories	169,254	155,288
Prepaid expenses and other assets	12,142	9,096
Prepaid income taxes	3,292	3,225
Income tax refund receivables	2,331	1,211
Total current assets	370,964	316,121
PROPERTY AND EQUIPMENT:		
Land and land improvements	26,940	19,877
Buildings	150,726	147,356
Manufacturing equipment	205,911	197,651
Furniture and fixtures	52,649	49,528
Leasehold improvements	33,029	31,161
Construction-in-progress	40,454	32,896
Total property and equipment	509,709	478,469
Less accumulated depreciation	(197,941) (185,649)
Property and equipment — net	311,768	292,820
OTHER ASSETS:		
Intangible assets:		
Developed technology — net of accumulated amortization — 2018 — \$86,023 and 2017 –		167,771
Other — net of accumulated amortization — 2018 — \$43,246 and 2017 — \$38,127	66,188	59,553
Goodwill Deformed income tox assets	248,998	238,147
Deferred income tax assets Other assets	2,318 58,075	2,359 35,040
Onici assets	30,073	<i>55</i> ,0 1 0
Total other assets	608,459	502,870

TOTAL \$1,291,191 \$1,111,811

See condensed notes to consolidated financial statements.

(continued)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS JUNE 30, 2018 AND DECEMBER 31, 2017 (In thousands)

LIABILITIES AND STOCKHOLDERS' EQUITY	June 30, 2018 (unaudited)	December 31, 2017
CURRENT LIABILITIES: Trade payables Accrued expenses Current portion of long-term debt Income taxes payable	\$50,823 65,838 21,985 948	\$34,931 58,932 19,459 2,298
Total current liabilities	139,594	115,620
LONG-TERM DEBT	391,582	259,013
DEFERRED INCOME TAX LIABILITIES	23,148	23,289
LONG-TERM INCOME TAXES PAYABLE	4,846	4,846
LIABILITIES RELATED TO UNRECOGNIZED TAX BENEFITS	2,746	2,746
DEFERRED COMPENSATION PAYABLE	11,620	11,181
DEFERRED CREDITS	2,332	2,403
OTHER LONG-TERM OBLIGATIONS	16,069	16,379
Total liabilities	591,937	435,477
COMMITMENTS AND CONTINGENCIES (Notes 5, 10, 11, and 14)		
STOCKHOLDERS' EQUITY: Preferred stock — 5,000 shares authorized as of June 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 June 30, 2018 - 50,635 and December 31, 2017 - 50,248	359,570	353,392
Retained earnings Accumulated other comprehensive income	337,618 2,066	321,408 1,534
Total stockholders' equity	699,254	676,334
TOTAL	\$1,291,191	\$1,111,811
See condensed notes to consolidated financial statements.		(concluded)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF INCOME FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2017 (In thousands, except per share amounts - unaudited)

			Six Months Ended June 30,	
NET SALES	2018 \$224,810	2017 \$186,549	2018 \$427,844	2017 \$357,618
COST OF SALES	124,801	102,408	239,779	197,535
GROSS PROFIT	100,009	84,141	188,065	160,083
OPERATING EXPENSES: Selling, general and administrative Research and development Contingent consideration expense (benefit) Acquired in-process research and development	69,095 15,316 178 306	57,409 13,313 (18)	134,007 29,638 219 306	115,180 25,838 19 75
Total operating expenses	84,895	70,779	164,170	141,112
INCOME FROM OPERATIONS	15,114	13,362	23,895	18,971
OTHER INCOME (EXPENSE): Interest income Interest expense Gain on bargain purchase Other income (expense) - net	-	89 (1,639) (669)	_	172 (4,345) 11,574 434
Other income (expense) — net	(3,549)	(2,049)	(5,970)	7,835
INCOME BEFORE INCOME TAXES	11,565	11,313	17,925	26,806
INCOME TAX EXPENSE	624	1,830	1,715	2,520
NET INCOME	\$10,941	\$9,483	\$16,210	\$24,286
EARNINGS PER COMMON SHARE: Basic	\$0.22	\$0.19	\$0.32	\$0.51
Diluted	\$0.21	\$0.19	\$0.31	\$0.50
AVERAGE COMMON SHARES: Basic	50,473	49,957	50,376	47,406
Diluted	52,154	51,188	52,033	48,516

See condensed notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2017 (In thousands - unaudited)

	Three Months		Six Montl	ns Ended
	Ended June 30,		June 30,	
	2018	2017	2018	2017
Net income	\$10,941	\$9,483	\$16,210	\$24,286
Other comprehensive income (loss):				
Cash flow hedges	881	(527)	2,873	310
Less income tax benefit (expense)	(226)	205	(738)	(121)
Foreign currency translation adjustment	(4,195)	1,425	(1,603)	2,205
Less income tax expense	_	_		(252)
Total other comprehensive income (loss)	(3,540)	1,103	532	2,142
Total comprehensive income	\$7,401	\$10,586	\$16,742	\$26,428

See condensed notes to consolidated financial statements.

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2018 AND 2017 (In thousands - unaudited)

(III tilousanus - unauditeu)	Six Month	hs Ended	
	June 30, 2018	2017	
CASH FLOWS FROM OPERATING ACTIVITIES: Net income	\$16,210	\$ 24,286	
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	32,779	25,709	
Gain on bargain purchase	_	(11,574)
Loss on sales and/or abandonment of property and equipment	371	234	
Write-off of patents and intangible assets	86	19	
Acquired in-process research and development	306	75	
Amortization of deferred credits	(71)	(76)
Amortization of long-term debt issuance costs	402	343	
Deferred income taxes	_	(295)
Stock-based compensation expense	2,821	1,691	
Changes in operating assets and liabilities, net of effects from acquisitions:			
Trade receivables	(27,947)	(13,248)
Other receivables	966	(114)
Inventories	(7,189)	(2,160)
Prepaid expenses and other current assets	(3,105)	(1,230)
Prepaid income taxes	(100)	(92)
Income tax refund receivables	(1,146)	294	
Other assets	(751)	(1,500)
Trade payables	15,767	3,664	
Accrued expenses	7,467	7,421	
Income taxes payable	(2,076)	(301)
Deferred compensation payable	438	513	
Other long-term obligations	(179)	907	
Total adjustments	18,839	10,280	
Net cash provided by operating activities	35,049	34,566	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures for:			
Property and equipment	(31,559)	(17,782)
Intangible assets	(1,755)	(1,082)
Proceeds from the sale of property and equipment	4	3	
Issuance of note receivable	(10,500)		
Cash paid in acquisitions, net of cash acquired	(118,654)	(54,809)
Net cash used in investing activities	(162,464)	(73,670)
See condensed notes to consolidated financial statements.		(continue	d)

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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2018 AND 2017 (In thousands - unaudited)

	Six Mont June 30,	ths Ended	
	2018	2017	
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	\$3,251	\$ 140,989	
Offering costs		(815)
Proceeds from issuance of long-term debt	320,827		,
Payments on long-term debt		(179,359)
Contingent payments related to acquisitions	(130)	(30)
Net cash provided by financing activities	138,121	57,644	
EFFECT OF EXCHANGE RATES ON CASH	470	(36)
NET INCREASE IN CASH AND CASH EQUIVALENTS	11,176	18,504	
CASH AND CASH EQUIVALENTS:			
Beginning of period	32,336	19,171	
	* 10 510	* 27 (77	
End of period	\$43,512	\$37,675	
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for:			
Interest (net of capitalized interest of \$314 and \$240, respectively)	\$5,714	\$4,386	
Income taxes	\$5,141	\$ 2,678	
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Property and equipment purchases in accounts payable	\$3,943	\$1,560	
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Acquisition purchases in accrued expenses and other long-term obligations	\$ —	\$6,000	
Merit common stock surrendered (32 and 0 shares, respectively) in exchange for exercise of stock options	\$1,684	\$ —	
Stock options			
See condensed notes to consolidated financial statements.		(conclude	ed)
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MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

- 1. Basis of Presentation. The interim consolidated financial statements of Merit Medical Systems, Inc. ("Merit," "we" or "us") for the three and six-month periods ended June 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 June 30, 2018 and December 31, 2017, and our results of operations and cash flows for the three and six-month periods ended June 30, 2018 and 2017. The results of operations for the three and six-month periods ended June 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 June 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	June 30,	December 31,
	2018	2017
Finished goods	\$101,092	\$86,555
Work-in-process	20,962	12,799
Raw materials	47,200	55,934

Total Inventories \$169,254 \$155,288

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

	Three Months		Six Months	
	Ended J	June 30,	Ended J	June 30,
	2018	2017	2018	2017
Cost of sales	\$232	\$168	\$416	\$264
Research and development	147	100	271	152
Selling, general and administrative	1,186	846	2,134	1,275
Stock-based compensation expense before taxes	\$1,565	\$1,114	\$2,821	\$1,691

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 June 30, 2018, the total remaining unrecognized compensation cost related to non-vested stock options, net of expected forfeitures, was approximately \$22.4 million and is expected to be recognized over a weighted average period of 3.46 years.

During the three and six-month periods ended June 30, 2018, we granted stock-based awards representing 200,000 and 692,002 shares of our common stock, respectively. During the three and six-month periods ended June 30, 2017,

we granted stock-based awards representing approximately 1.28 million shares of our common stock. 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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Six Months Ended June 30, 2018 2017

Risk-free interest rate 2.63% - 2.77% 1.77% - 1.79% Expected option life 5.0 years 5.0 years

Expected dividend yield — —

Expected price volatility 34.06% - 34.32% 33.81% - 34.03%

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 M Net Income	onths Shares	Per Share Amount		ths Shares	Per Share Amount
Period ended June 30, 2018: Basic EPS Effect of dilutive stock options and warrants	\$10,941	50,473 1,681		\$16,210	50,376 1,657	\$ 0.32
Diluted EPS	\$10,941	52,154	\$ 0.21	\$16,210	52,033	\$ 0.31
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		535			359	
Period ended June 30, 2017: Basic EPS Effect of dilutive stock options and warrants	\$9,483	49,957 1,231	\$ 0.19	\$24,286	47,406 1,110	\$ 0.51
Diluted EPS	\$9,483	51,188	\$ 0.19	\$24,286	48,516	\$ 0.50
Stock options excluded from the calculation of common stock equivalents as the impact was anti-dilutive		1,007			552	

5. Acquisitions. 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 a follows (in thousands):

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Net Assets Acquired

Inventories \$971

Intangibles

Developed technology 4,840 Customer list 120 Trademarks 400 Goodwill 938

Total net 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 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 TargetingTM 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 segment since the acquisition date. During the period from April 6, 2018 to June 30, 2018, our net sales of NinePoint products were approximately \$1.1 million. We believe the NinePoint products will enhance the product offerings of our Endotek 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, 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 a rate of 9% and is collateralized by NinePoint's rights, interest and title to the NvisionVLE® Imaging System and any other product owned or licensed by 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 six-month periods ended June 30, 2018, our net sales of BD products were approximately \$12.2 million and \$18.5 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 \$41,000 and \$1.8 million for the three and six-month periods ended June 30, 2018. The following table summarizes the

preliminary purchase price allocated to the assets acquired from BD (in thousands):

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	Preliminary	Adjustments	Revised
	Allocation	(1)	Allocation
Inventories	\$ 6,039	\$ (235)	\$5,804
Property and equipment	581	167	748
Intangibles			
Developed technology	79,900	(5,900)	74,000
Customer list	3,500	700	4,200
Trademarks	4,700	200	4,900
Goodwill	5,387	5,226	10,613
Total net assets acquired	\$ 100,107	\$ 158	\$100,265

Under U.S. GAAP, measurement period adjustments are recognized on a prospective basis in the period of change, instead of restating prior periods. There was no impact to reported earnings in connection with these measurement (1) period adjustments for the periods presented. Amounts represent adjustments to the preliminary purchase price allocation first presented in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 resulting from a final working capital adjustment and our ongoing activities with respect to finalizing asset valuations for this acquisition.

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 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 tax liabilities	(1,901)
Total liabilities assumed	(2,864)
Total net assets acquired	\$11,290)

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 segment since the acquisition date. During the three and six months ended June 30, 2018, our net sales of ITL products were approximately \$2.0 million and \$4.2 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.

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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):

Net Assets Acquired

Inventories \$594

Intangibles

Developed technology 14,920 Customer list 120 Goodwill 6,366

Total net 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 six months ended June 30, 2018, our net sales of Osseon products were approximately \$588,000 and \$1.1 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 net assets acquired (in thousands):

Net Assets Acquired

Inventories \$979 Property and equipment 58

Intangibles

Developed technology 5,400 Customer list 200 Goodwill 203

Total net 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 SAFECVADTM 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 and liabilities assumed (in thousands):

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Net Assets Acquired

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.

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 six months ended June 30, 2018, our net sales of the Argon critical care products were approximately \$11.2 million and \$23.7 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):

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Assets Acquired	
Cash and cash equivalents	\$1,436
Trade receivables	8,351
Inventories	11,222
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	2,200
Customer lists	1,500
Trademarks	900
Total assets acquired	29,570
Liabilities Assumed	
Trade payables	(2,414)
Accrued expenses	(5,083)
Deferred income tax liabilities	(934)
Total liabilities assumed	(8,431)
Total net assets acquired	21,139
Gain on bargain purchase (1)	(11,039)
Total purchase price	\$10,100
rotal 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 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 6.0 years.

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 segment since the acquisition date. During the three and six months ended June 30, 2018, our net sales of the products acquired from Catheter Connections were approximately \$3.1 million and \$6.3 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):

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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)
Net assets acquired	\$38,00	0

We are amortizing the Catheter Connections developed technology asset over 12 years, the related trademarks over 10 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.

On July 6, 2016, we acquired all of the issued and outstanding shares of DFINE Inc. ("DFINE"). The DFINE acquisition added a line of vertebral augmentation products for the treatment of vertebral compression fractures, as well as medical devices used to treat metastatic spine tumors. We made an initial payment of \$97.5 million to certain DFINE stockholders on July 6, 2016 and paid approximately \$578,000 related to a net working capital adjustment subject to review by Merit and the preferred stockholders of DFINE. We accounted for the acquisition as a business combination. Acquisition-related costs during the year ended December 31, 2016, which are included in selling, general, and administrative expenses were approximately \$1.6 million. The results of operations related to this acquisition have been included in our cardiovascular segment since the acquisition date. During the three and six months ended June 30, 2018, our net sales of DFINE products were approximately \$7.2 million and \$14.5 million, respectively. It is not practical to separately report the earnings related to the DFINE acquisition, as we cannot split out sales costs related to DFINE products, principally because our sales representatives are selling multiple products (including DFINE products) in the cardiovascular business segment. The purchase price was allocated to the net tangible and intangible assets acquired and liabilities assumed, based on estimated fair values, as follows (in thousands):

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Assets Acquired	
Trade receivables	\$4,054
Other receivables	6
Inventories	8,585
Prepaid expenses and other assets	630
Property and equipment	1,630
Other long-term assets	145
Intangibles	
Developed technology	67,600
Customer lists	2,400
Trademarks	4,400
Goodwill	24,818
Total assets acquired	114,268
Liabilities Assumed	
Trade payables	(1,790)
Accrued expenses	(5,298)
Deferred income tax liabilities - current	(701)
Deferred income tax liabilities - noncurrent	(10,844)
Total liabilities assumed	(18,633)

Net assets acquired, net of cash received of \$1,327 \$95,635

The gross amount of trade receivables we acquired in the acquisition was approximately \$4.3 million, of which approximately \$224,000 was expected to be uncollectible or returned. With respect to the DFINE assets, we are amortizing developed technology over 15 years and customer lists on an accelerated basis over nine years. While U.S. trademarks can be renewed indefinitely, we currently estimate that we will generate cash flow from the acquired trademarks for a period of 15 years from the acquisition date. The total weighted-average amortization period for these acquired intangible assets is 14.8 years.

On February 4, 2016, we purchased the HeRO® Graft device and other related assets from CryoLife, Inc., a developer of medical devices based in Kennesaw, Georgia ("CryoLife"). The HeRO Graft is a fully subcutaneous vascular access system intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have failing fistulas, grafts or are catheter dependent due to a central venous blockage. The purchase price was \$18.5 million, which was paid in full during 2016. We accounted for this acquisition as a business combination. The purchase price was allocated as follows (in thousands):

Assets Acquired

Inventories \$2,455 Property and equipment 290

Intangibles

Developed technology 12,100
Trademarks 700
Customers Lists 400
Goodwill 2,555

Total assets acquired \$18,500

We are amortizing the developed HeRO Graft technology asset over 10 years, the related trademarks over 5.5 years, and the associated customer lists over 12 years. We have estimated the weighted average life of the intangible HeRO

Graft assets acquired to be approximately 9.8 years. Acquisition-related costs related to the HeRO Graft device and other related assets during the year ended December 31, 2016, which are included in selling, general and administrative expenses, 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 six months ended June 30, 2018, our net sales of the products acquired from CryoLife were approximately \$2.2 million and \$4.2 million, respectively. It is not practical to separately report the earnings related to the products acquired from CryoLife, as

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we cannot split out sales costs related to those products, principally because our sales representatives are selling multiple products (including the HeRO Graft device) in the cardiovascular business segment.

The following table summarizes our consolidated results of operations for the six-month period ended June 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):

Six Months Ended June 30, 2017 As Pro Reported Forma \$357,618 \$360,378 24,286 12,444

Earnings per common share:

Net sales

Net income

Basic \$0.51 \$0.26 Diluted \$0.50 \$0.26

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.

In accordance with Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 606"), we recognize revenue when a customer obtains control of promised goods. The amount of revenue recognized reflects the consideration we to receive in exchange for these goods. To achieve this core principle, we apply the following five steps:

1. 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

^{*} The pro forma results for the three-month periods ended June 30, 2018 and 2017 and the six-month period ended June 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.

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 relate to delivering

- 2. 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 3. evaluate if collectability is reasonably assured. None of our contracts as of June 30, 2018 contained a significant financing

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component. Further, our methodology to estimate and recognize variable consideration is consistent with the requirements of ASC 606. 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 4. performance obligations in our contracts with customers. As such, we recognize revenue upon delivery 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 5.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.

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

	Three Months Ended June 30,			Three Months Ended June 30,			
	2018)18			2017		
	United	International Total		United International Total		Total	
	States			States	international Total		
Cardiovascular							
Stand-alone devices	\$50,941	\$ 41,555	\$92,496	\$37,202	\$ 33,854	\$71,056	
Custom kits and procedure trays	23,667	10,325	33,992	24,271	7,526	31,797	
Inflation devices	8,160	16,145	24,305	8,042	12,747	20,789	
Catheters	16,704	22,670	39,374	16,022	16,407	32,429	
Embolization devices	5,094	7,630	12,724	5,593	6,565	12,158	
CRM/EP	11,758	1,738	13,496	10,264	1,170	11,434	
Total	116,324	100,063	216,387	101,394	78,269	179,663	
Endoscopy							
Endoscopy devices	8,121	302	8,423	6,712	174	6,886	
Total	\$124,445	\$ 100,365	\$224,810	\$108,106	\$ 78,443	\$186,549	

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	Six Months Ended June 30, 2018			Six Months Ended June 30, 2017		
	United States	International Total		United States	International Total	
Cardiovascular						
Stand-alone devices	\$94,953	\$ 80,789	\$175,742	\$73,366	\$ 61,343	\$134,709
Custom kits and procedure trays	45,984	21,280	67,264	45,737	14,935	60,672
Inflation devices	15,828	30,896	46,724	16,017	23,279	39,296
Catheters	31,974	41,265	73,239	31,151	31,454	62,605
Embolization devices	10,126	15,184	25,310	11,134	13,551	24,685
CRM/EP	20,596	3,366	23,962	20,011	2,440	22,451
Total	219,461	192,780	412,241	197,416	147,002	344,418
Endoscopy						
Endoscopy devices	15,040	563	15,603	12,806	394	13,200
Total	\$234,501	\$ 193,343	\$427,844	\$210,222	\$ 147,396	\$357,618

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 six-month periods ended June 30, 2018 and 2017, are as follows (in thousands):

	Three Mo Ended Jur		Six Months Ended June 30,		
	2018	2017	2018	2017	
Net Sales (1)					
Cardiovascular	\$216,387	\$179,663	\$412,241	\$344,418	
Endoscopy	8,423	6,886	15,603	13,200	
Total net sales	\$224,810	\$186,549	\$427,844	\$357,618	
Operating Income (1)					
Cardiovascular	\$12,663	\$11,493	\$19,060	\$15,475	
Endoscopy	2,451	1,869	4,835	3,496	
Total operating income	\$15,114	\$13,362	\$23,895	\$18,971	

⁽¹⁾ Sales and operating income have been adjusted from prior disclosure to reflect changes in product classifications between our operating segments, which were made to be consistent with updates in the management of our product portfolios in 2018.

8. Recently Issued Financial Accounting Standards

Recently Adopted

In October 2016, the Financial Accounting Standards Board (the "FASB") issued 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.

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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.

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 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. We are currently evaluating the anticipated impact of adopting ASU 2018-02 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. ASU 2016-02 provides that lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. We are assessing the impact that ASU 2016-02 is anticipated to have on our consolidated financial statements. We currently expect that most of our operating lease commitments will be subject to the new standard and recognized as lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

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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 ("SAB 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 June 30, 2018, the amounts recorded for the 2017 Tax Act remain provisional and may be impacted by further analysis and subsequently issued guidance.

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 six months ended June 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 June 30, 2018 and 2017 was a tax expense of approximately \$624,000 and \$1.8 million, respectively, which resulted in an effective tax rate of 5.4% and 16.2%, respectively. Our provision for income taxes for the six months ended June 30, 2018 and 2017 was a tax expense of approximately \$1.7 million and \$2.5 million, respectively, which resulted in an effective tax rate of 9.6% and 9.4%, respectively. The decrease in the effective income tax rate for the second quarter of 2018 compared to the second quarter of 2017 was primarily caused by a decrease in the federal statutory tax rate, as well as a discrete tax benefit related to share-based payment awards. Despite the decrease resulting from these items, the effective tax rate for the six months ended June 30, 2018 is relatively unchanged when compared to the corresponding period in 2017 due primarily to the nontaxable gain on the bargain purchase recorded in connection with the 2017 acquisition of the Argon critical care division.

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

	June 30,	December
	2018	31, 2017
2016 Term loan	\$80,000	\$85,000
2016 Revolving credit loans	327,000	187,000
Collateralized debt facility	6,985	6,959
Less unamortized debt issuance costs	(418)	(487)
Total long-term debt	413,567	278,472
Less current portion	21,985	19,459

\$391,582 \$259,013

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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.

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

Maximum Consolidated Total Leverage Ratio (as

- (1) 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.

Minimum level of Consolidated Net Income (as

- (3) defined in the Second Amended Credit Agreement) for certain periods, and subject to certain adjustments. Maximum level of the aggregate amount of all Facility
- (4) 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 June 30, 2018, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of June 30, 2018, we had outstanding borrowings of approximately \$407 million under the Second Amended Credit Agreement, with available borrowings of approximately \$47.8 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of June 30, 2018 was a fixed rate of 2.87% on \$175 million as a result an interest rate swap

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(see Note 11) and a variable floating rate of 3.84% on \$232 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 March 14, 2018, we renewed our loan agreement with HSBC Bank USA, National Association ("HSBC Bank") whereby HSBC Bank agreed to provide us with a loan in the amount of approximately \$7.0 million. The loan matures on July 10, 2018, with an extension available at our option, subject to certain conditions. The loan agreement bears interest at the three-month London Inter-Bank Offered Rate ("LIBOR") plus 1.0%, which resets quarterly. 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 June 30, 2018, our interest rate on the loan was a variable rate of 3.26%.

Future Payments

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

Years Ending	Future
Tears Ending	Minimum
December 31	Principal
December 31	Payments
Remaining 2018	\$ 14,485
2019	15,000
2020	17,500
2021	367,000
Total future minimum principal payments	\$413,985

11. Derivatives

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 June 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 June 30, 2018 was an asset of approximately \$8.0 million, which was partially offset by approximately \$2.1 million in

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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, Korea 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 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 100 cash flow foreign currency hedges every month. As of June 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 2,410 **Swiss Franc** CHF 1,158 Chinese Renminbi CNY 66,000 Danish Krone DKK 11,650 Euro 12,870 EUR **British Pound** GBP 2,975 Mexican Peso MXN 94,275 Swedish Krona SEK 13,830

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 June 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):

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Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	8,400
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

Balance Sheet Presentation of Derivatives. As of June 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):

		Fair Val	ue
	Balance Sheet Location	June 30, 2018	December 31, 2017
Derivatives designated as hedging in	nstruments		
Assets			
Interest rate swap	Other assets (long-term)	\$8,047	\$ 5,749
Foreign currency forward contracts	Prepaid expenses and other assets	700	363
Foreign currency forward contracts	Other assets (long-term)	83	35
Liabilities Foreign currency forward contracts Foreign currency forward contracts	*	,	(468) (82)
Derivatives not designated as hedgin	ng instruments		
Assets			
Foreign currency forward contracts Liabilities	Prepaid expenses and other assets	\$1,097	\$ 223
Foreign currency forward contracts	Accrued expenses	(228)	(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):

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	recognin OC Three Month Ended	(Loss) nized CI			Amour Gain/(I reclass from A Three I Ended 30,	Loss) ified OCI Months
	30, 2018	2017			2018	2017
Derivative instrument	2016	2017		Location in state income		
Interest rate swaps	\$748	\$(893)	Interest Expense	\$ 357	\$ —
Foreign currency forward contracts				Revenue	(234) (41)
				Cost of sales	138	28
	recognin OC Six M	(Loss) nized CI Ionths d June		Location in state	Amour Gain/(I reclass from A Six Mo Ended 30, 2018	Loss) iffied OCI onths June
Derivative instrument				income		
Interest rate swaps	2,868	(507)	Interest Expense	570	(10)4
Foreign currency forward contracts	568	741		Revenue Cost of sales	(385 378) (40) (37)

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

As of June 30, 2018, approximately \$464,000, or \$345,000 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 June 30, 2018, approximately \$2.2 million, or \$1.6 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

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

		Three Months	Six Months
		Ended June 30,	Ended June 30,
		2018 2017	2018 2017
Derivative Instrument	Location in statements of income		
Foreign currency forward contracts	Other expense	\$3,153\$(1,834)	\$2,038\$(2,692)

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

Fair Value Measurements Using

Three Months

Description	Total Fair Quotesti gmiciasaint Value at activeoloxanketble June 30, (Level 2018 1) (Level 2)		Significant unobservable in (Level 3)	puts
Interest rate contracts ⁽¹⁾ Foreign currency contract assets, current and long-term ⁽²⁾ Foreign currency contract liabilities, current and long-term ⁽³⁾	\$8,047)	\$ \$ \$	<u> </u>
	Fair Value Measu	irements	Using	
Description	Total Fair Quotesti gmicresaint value at activeobranketsle in December (Level 2) (Level 2)		Significant unobservable in (Level 3)	puts

- (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 at each reporting period with the change in fair value recognized within operating expenses in the accompanying consolidated statements of income. We measure the initial liability and re-measure the liability on a recurring basis using Level 3 inputs as defined under authoritative guidance for fair value measurements. Changes in the fair value of our contingent consideration liability during the three and six-month periods ended June 30, 2018 and 2017, consisted of the following (in thousands):

	111100 111	JII	om mone	no Enaca
	Ended Ju	ne 30,	June 30,	
	2018	2017	2018	2017
Beginning balance	\$10,928	\$705	\$10,956	\$683
Contingent consideration liability recorded as the result of acquisitions (see Note 5)	_	4,900	_	4,900
Fair value adjustments recorded to income during the period	99	(18)	86	19
Contingent payments made	(115)	(15)	(130)	(30)
Ending balance	\$10,912	\$5,572	\$10,912	\$5,572

Six Months Ended

As of June 30, 2018, approximately \$10.6 million in contingent consideration liability was included in other long-term obligations and approximately \$301,000 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

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defined under authoritative guidance for fair value measurements, and we recorded a contingent receivable asset, which as of June 30, 2018 and December 31, 2017 had a value of approximately \$474,000 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 six months ended June 30, 2018, we recorded a loss on the contingent receivable of approximately \$79,000 and \$132,000, respectively and received payments of approximately \$0 and \$153,000, respectively. As of June 30, 2018, approximately \$184,000 was included in other long-term assets and approximately \$290,000 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 June 30, 2018 and December 31, 2017 (amounts in thousands):

Contingent consideration asset or liability	Fair value at June 30, 2018	Valuation technique	Unobservable inputs	Range
Revenue-based payments contingent liability	\$ 10,912	Discounted cash flow	Discount rate Projected year of payments	9.9% - 15% 2018-2037
Contingent receivable asset	\$ 474	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	10% 54% 2018-2019
Contingent consideration asset or liability	Fair value at December 31, 2017	Valuation technique	Unobservable inputs	Range
Revenue-based payments contingent liability	\$ 10,956	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	9.9% - 15% 100% 2018-2037
Contingent receivable asset	\$ 760	Discounted cash flow	Discount rate Probability of milestone payment Projected year of payments	10% 75% 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 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 six-month periods ended June 30, 2018, we had losses of approximately \$29,000 and \$86,000, respectively, compared to losses of approximately \$1,000 and \$19,000 for the three and six-month periods ended June

30, 2017, respectively, related to the measurement of non-financial assets at fair value on a nonrecurring basis subsequent to their initial recognition.

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.

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

	2018
Goodwill balance at January 1	\$238,147
Effect of foreign exchange	(906)
Additions as the result of acquisitions	11,757
Goodwill balance at June 30	\$248,998

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

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

\mathcal{E}	June 30,	2018	
	Gross Carrying Amount	Accumulate Amortizatio	Carrying
Patents	\$18,196	\$ (4,334	\$ 13,862
Distribution agreements	8,192	(5,278) 2,914
License agreements	23,845	(6,419) 17,426
Trademarks	21,516	(5,550) 15,966
Covenants not to compete	1,028	(985) 43
Customer lists	35,737	(20,680) 15,057
In-process technology	920		920
Total		\$ (43,246	\$66,188
	Decembe	er 31, 2017	
	Gross Carrying Amount	er 31, 2017 Accumulated Amortization	('arryıng
Patents	Gross Carrying Amount	Accumulated	Carrying
	Gross Carrying Amount	Accumulated Amortization	Carrying Amount \$ 12,791
Patents Distribution agreements License agreements	Gross Carrying Amount \$16,528 7,262	Accumulated Amortization \$ (3,737)	Carrying Amount \$12,791
Distribution agreements	Gross Carrying Amount \$16,528 7,262	Accumulated Amortization \$ (3,737) (4,686)	Carrying Amount \$12,791 2,576
Distribution agreements License agreements	Gross Carrying Amount \$16,528 7,262 23,783	Accumulated Amortization \$ (3,737) (4,686) (5,568)	Carrying Amount \$ 12,791 2,576 18,215
Distribution agreements License agreements Trademarks	Gross Carrying Amount \$16,528 7,262 23,783 16,224	Accumulated Amortization \$ (3,737) (4,686) (5,568) (4,686)	Carrying Amount \$ 12,791 2,576 18,215 11,538
Distribution agreements License agreements Trademarks Covenants not to compete	Gross Carrying Amount \$16,528 7,262 23,783 16,224 1,028	Accumulated Amortization \$ (3,737) (4,686) (5,568) (4,686) (968)	Carrying Amount \$ 12,791 2,576 18,215 11,538 60

Aggregate amortization expense for the three and six-month periods ended June 30, 2018 was approximately \$10.4 million and \$18.9 million, respectively. Aggregate amortization expense for the three and six-month periods ended June 30, 2017 was approximately \$6.2 million and \$12.4 million, respectively.

\$97,680 \$ (38,127) \$59,553

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

Year Ending December 31 Remaining 2018 \$20,132

Total

2019	39,154
2020	37,881
2021	30,488
2022	28,688
30	

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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 six-month periods ended June 30, 2018 were approximately \$1.6 million and \$3.3 million, respectively.

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 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 approximately \$816,000 in other direct cost incurred and paid by us in connection with this equity offering. The net proceeds from the offering were used primarily to repay outstanding indebtedness under our Second Amended Credit Agreement (including our term loan and revolving credit loans).
- 16. Subsequent Events. 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 \$10.4 million in underwriting discounts and commissions, and we paid approximately \$500,000 in other direct costs incurred in connection with this equity offering. The net proceeds from the offering were used primarily to repay revolving credit loans under our Second Amended Credit Agreement.

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

Disclosure Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements in this report, other than statements of historical fact, are "forward-looking statements" for purposes of these provisions, including, without limitation, any projections of earnings, revenues or other financial items, any statements of the plans and objectives of our management for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or any assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "intends," "seeks," "believes," "estimates," "potential," "forecasts," "o forms of these words or similar words or expressions, or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct. Actual results will likely differ, and could differ materially, from those projected or assumed in the forward-looking statements. Prospective investors are cautioned not to unduly rely on any such forward-looking statements.

Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the following:

risks relating to managing growth, particularly if accomplished through acquisitions and the integration of acquired businesses;

risks relating to protecting our intellectual property;

claims by third parties that we infringe their intellectual property rights, which could cause us to incur significant legal or licensing expenses and prevent us from selling our products;

greater scrutiny and regulation by governmental authorities, including risks relating to the subpoena we received in October 2016 from the U.S. Department of Justice seeking information on our marketing and promotional practices; risks relating to physicians' use of our products in unapproved circumstances;

regulatory clearance processes of the FDA and other governmental authorities and any failure to obtain and maintain required regulatory clearances and approvals;

disruption of our critical information systems or material breaches in the security of our systems:

failure to comply with export control laws, customs laws, domestic procurement laws, sanctions laws and other laws governing our operations in the U.S. and other countries, which could subject us to civil or criminal penalties, other remedial measures and legal expenses;

•risks relating to significant adverse changes in, or our failure to comply with, governing regulations; restrictions and limitations in our debt agreements and instruments, which could affect our ability to operate our

business and our liquidity;

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;

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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;

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 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;

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;

4imits 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

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. Our actual results will likely differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates. 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

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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 "TM" 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 single-use medical products for interventional and diagnostic procedures. For financial reporting purposes, we report our operations in two operating segments: cardiovascular and endoscopy. Our cardiovascular segment consists of cardiology and radiology devices, which assist in diagnosing and treating coronary arterial disease, peripheral vascular disease and other non-vascular diseases and includes 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 June 30, 2018, we reported sales of approximately \$224.8 million, up approximately \$38.3 million or 20.5%, over sales from the three-month period ended June 30, 2017 of approximately \$186.5 million. For the six-month period ended June 30, 2018, we reported sales of approximately \$427.8 million, up approximately \$70.2 million or 19.6%, over sales from the six-month period ended June 30, 2017 of approximately \$357.6 million.

Gross profit as a percentage of sales decreased to 44.5% for the three-month period ended June 30, 2018 as compared to 45.1% for the three-month period ended June 30, 2017. Gross profit as a percentage of sales decreased to 44.0% for the six-month period ended June 30, 2018 as compared to 44.8% for the six-month period ended June 30, 2017.

Net income for the three-month period ended June 30, 2018 was approximately \$10.9 million, or \$0.21 per share, as compared to \$9.5 million, or \$0.19 per share, for the three-month period ended June 30, 2017. Net income for the six-month period ended June 30, 2018 was approximately \$16.2 million, or \$0.31 per share, as compared to \$24.3 million, or \$0.50 per share, for the six-month period ended June 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," we believe that our business in 2018 will be impacted by the following recent events and trends:

In February 2018, we acquired certain divested assets from BD for an aggregate purchase price of \$100.3 million. The acquired assets 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. During the three and six-month periods ended June 30, 2018, our net sales of BD products were approximately \$12.2 million and \$18.5 million, respectively.

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 TargetingTM using Optical Coherence Tomography (OCT) and (b) acquired an option to purchase up to 100% of the outstanding equity in NinePoint both in exchange for total consideration of \$10.0 million. In addition, we made a loan to NinePoint for \$10.5 million. We believe the NinePoint products will enhance the product offerings of our Endotek division (in our endoscopy segment) and will be another step to adding 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. During the period from April 6, 2018 to June 30, 2018, our net sales of NinePoint products were approximately \$1.1 million.

In May 2018, we entered into an agreement for the acquisition of product distribution agreements for the DirectACCESS FirstChoiceTM Ultra High Pressure PTA Balloon Catheter and executed a distribution agreement for the QXMédical Q50® PLUS Stent Graft Balloon Catheter.

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A competitor recently experienced substantial global supply shortages due to internal issues, which has resulted in increased demand for our Merit Laureate® Hydrophilic Guide Wires, our offering of microcatheters (including the Merit Maestro®, SwiftNINJA® and the recently introduced PursueTM Microcatheter), our Impress® Diagnostic Catheters and our vascular sheaths (including the recently introduced Prelude IDealTM and PreludeEASETM product offerings).

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.

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Results of Operations

The following table sets forth certain operational data as a percentage of sales for the three and six-month periods ended June 30, 2018 and 2017, as indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net sales	100%	100%	100%	100%
Gross profit	44.5	45.1	44.0	44.8
Selling, general and administrative expenses	30.7	30.8	31.3	32.2
Research and development expenses	6.8	7.1	6.9	7.2
Contingent consideration expense (benefit)	0.1	0.0	0.1	0.0
Acquired in-process research and development expenses	0.1	0.0	0.1	0.0
Income from operations	6.7	7.2	5.6	5.3
Other income (expense) - net	(1.6)	(1.1)	(1.4)	2.2
Income before income taxes	5.1	6.1	4.2	7.5
Net income	4.9	5.1	3.8	6.8

Sales

Sales for the three-month period ended June 30, 2018 increased by 20.5%, or approximately \$38.3 million, compared to the corresponding period in 2017. Sales for the six-month period ended June 30, 2018 increased by 19.6%, or approximately \$70.2 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 six-month periods ended June 30, 2018 and 2017 (in thousands, other than percentage changes):

		Three Months Ended June 30,			Six Months Ended June 30,		
	% Change	2018	2017	% Change	2018	2017	
Cardiovascular	_						
Stand-alone devices	30.2%	\$92,496	\$71,056	30.5%	\$175,742	\$134,709	
Custom kits and procedure trays	6.9%	33,992	31,797	10.9%	67,264	60,672	
Inflation devices	16.9%	24,305	20,789	18.9%	46,724	39,296	
Catheters	21.4%	39,374	32,429	17.0%	73,239	62,605	
Embolization devices	4.7%	12,724	12,158	2.5%	25,310	24,685	
CRM/EP	18.0%	13,496	11,434	6.7%	23,962	22,451	
Total	20.4%	216,387	179,663	19.7%	412,241	344,418	
Endoscopy							
Endoscopy devices	22.3%	8,423	6,886	18.2%	15,603	13,200	
Total	20.5%	\$224,810	\$186,549	19.6%	\$427,844	\$357,618	

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 June 30, 2018 were approximately \$216.4 million, up 20.4% when compared to the corresponding period for 2017 of approximately \$179.7 million. Sales for the three-month period ended June 30, 2018 were favorably affected by increased sales of (a) our stand-alone devices (particularly our MAPTM Merit Angioplasty Packs, Merit Laureate® Hydrophilic Guide Wires, EN Snare® Endovascular Snare Systems, and wires, as well as sales from products acquired in connection with our acquisitions including the BD product lines, Catheter Connections, Osseon, and Laurane) of approximately \$21.4 million, up 30.2% 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 approximately \$6.9 million, up 21.4% from the corresponding period for 2017; (c) our custom kits and procedure trays of approximately \$2.2 million (which includes sales from our acquisition of ITL), up 6.9%

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from the corresponding period for 2017; and (d) inflation devices (particularly our basixTOUCH® and BasixCompak® product lines) of approximately \$3.5 million, up 16.9% from the corresponding period for 2017.

Our cardiovascular sales for the six-month period ended June 30, 2018 were approximately \$412.2 million, up 19.7%, when compared to the corresponding period for 2017 of approximately \$344.4 million. Sales for the six-month period ended June 30, 2018 were favorably affected by increased sales of (a) our stand-alone devices (particularly our MAPTM Merit Angioplasty Packs, Merit Laureate® Hydrophilic Guide Wires, EN Snare® Endovascular Snare Systems, Medallion® Syringes, stopcocks, 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 \$41.0 million, up 30.5% from the corresponding period for 2017; (b) catheters (particularly our ReSolve® Locking Drainage Catheters, Prelude® and Prelude® Radial Sheath product lines, and our Merit Maestro® Microcatheters) of approximately \$10.6 million, up 17.0% from the corresponding period for 2017; (c) our custom kits and procedure trays of approximately \$6.6 million (which includes sales from our acquisition of ITL), up 10.9% from the corresponding period for 2017; and (d) inflation devices (particularly our BASIXTouch® and BasixCompak® product lines) of approximately \$7.4 million, up 18.9% from the corresponding period for 2017.

Endoscopy Sales. Our endoscopy sales for the three-month period ended June 30, 2018 were approximately \$8.4 million, up 22.3%, when compared to sales in the corresponding period of 2017 of approximately \$6.9 million. Our endoscopy sales for the six-month period ended June 30, 2018 were approximately \$15.6 million, up 18.2%, when compared to sales in the corresponding period of 2017 of approximately \$13.2 million. In each case, the increase was primarily related to an increase in sales of our Elation® Balloon Dilator, products acquired from BD and products sold pursuant to our distribution agreement with NinePoint.

International Sales. International sales for the three-month period ended June 30, 2018 were approximately \$100.4 million, or 44.6% of net sales, up 27.9% when compared to the corresponding period in 2017. The increase in our international sales for the second quarter of 2018 compared to the second quarter of 2017 was primarily related to (a) sales increases in China of approximately \$6.7 million, or 35.4% when compared to the corresponding period in 2017, (b) sales increases in Japan of approximately \$2.3 million, or 24.8% 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 six-month period ended June 30, 2018 were approximately \$193.3 million, or 45.2% of net sales, up 31.2% when compared to the six-month period ended June 30, 2017. The increase in our international sales was primarily related to (a) sales increases in China of approximately \$12.6 million, or 34.3% when compared to the corresponding period in 2017, (b) sales increases in Japan of approximately \$3.8 million, or 21.7% 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 decreased to 44.5% for the three-month period ended June 30, 2018, compared to 45.1% for the three-month period ended June 30, 2017. Gross profit as a percentage of sales decreased to 44.0% for the six-month period ended June 30, 2018, compared to 44.8% for the six-month period ended June 30, 2017. These decreases were primarily due to increased amortization as a result of acquisitions, increased inventory obsolescence, and increased freight costs associated with filling our global pipeline.

Operating Expenses

Selling, General and Administrative Expense. Selling, general and administrative ("SG&A") expenses increased approximately \$11.7 million, or 20.4%, for the three-month period ended June 30, 2018 compared to the three-month period ended June 30, 2017. As a percentage of sales, SG&A expenses were 30.7% of sales for the three-month period

ended June 30, 2018, compared to 30.8% the three-month period ended June 30, 2017. SG&A expenses increased approximately \$18.8 million, or 16.3%, for the six-month period ended June 30, 2018 compared to the six-month period ended June 30, 2017. As a percentage of sales, SG&A expenses decreased to 31.3% of sales for the six-month period ended June 30, 2018, compared to 32.2% of sales for the six-month period ended June 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 June 30, 2018 were approximately \$15.3 million, up 15.0%, when compared to R&D expenses in the corresponding period

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of 2017 of approximately \$13.3 million. R&D expenses for the six-month period ended June 30, 2018 were approximately \$29.6 million, up 14.7%, when compared to R&D expenses in the corresponding period of 2017 of approximately \$25.8 million. This 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 six-month periods ended June 30, 2018 and 2017 (in thousands):

Three Months
Ended June 30,
2018 2017 2018 2017

Operating Income

Cardiovascular \$12,663 \$11,493 \$19,060 \$15,475 Endoscopy 2,451 1,869 4,835 3,496 Total operating income \$15,114 \$13,362 \$23,895 \$18,971

Cardiovascular Operating Income. Our cardiovascular operating income for the three-month period ended June 30, 2018 was approximately \$12.7 million, compared to operating income of approximately \$11.5 million for the three-month period ended June 30, 2017. Our cardiovascular operating income for the six-month period ended June 30, 2018 was approximately \$19.1 million, compared to operating income of approximately \$15.5 million for the six-month period ended June 30, 2017. The increase in cardiovascular operating income was primarily related to increased sales, which was partially offset by a lower gross margin percentage, acquisition and integration-related costs, increased headcount, increased amortization as a result of acquisitions, and foreign market expansion.

Endoscopy Operating Income. Our endoscopy operating income for the three-month period ended June 30, 2018 was approximately \$2.5 million, compared to approximately \$1.9 million for the three-month period ended June 30, 2017. Our endoscopy operating income for the six-month period ended June 30, 2018 was approximately \$4.8 million, compared to approximately \$3.5 million for the six-month period ended June 30, 2017. This increase was primarily the result of higher sales (principally related to sales of the NinePoint product of approximately \$1.1 million) and lower SG&A expenses as a percentage of sales.

Effective Tax Rate

Our effective income tax rate for the three-month periods ended June 30, 2018 and 2017 was 5.4%, and 16.2%, respectively. Our effective income tax rate for the six-month periods ended June 30, 2018 and 2017 was 9.6% and 9.4%, respectively. The decrease in the effective income tax rate for the second quarter of 2018 compared to the second quarter of 2017 was primarily caused by a decrease in the federal statutory tax rate, as well as a discrete tax benefit related to share-based payment awards. Despite the decrease resulting from these items, the effective tax rate for the six months ended June 30, 2018 is relatively unchanged when compared to the corresponding period in 2017 due to the nontaxable gain on the bargain purchase recorded in connection with the 2017 acquisition of the Argon critical care division.

Other Income (Expense)

Our other income (expense) for the three-month periods ended June 30, 2018 and 2017 was approximately \$(3.5) million, and \$(2.0) million, respectively. The increase in other expense was primarily a result of increased interest

⁽¹⁾ Operating income for the 2017 periods has been adjusted from prior disclosure to reflect changes in product classifications between our operating segments, which were made to be consistent with updates in the management of our product portfolios in 2018.

expense due to higher debt balances used to finance the BD and other acquisitions.

Our other income (expense) for the six-month periods ended June 30, 2018 and 2017 was approximately \$(6.0) million, and \$7.8 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 debt balances used to finance the BD and other acquisitions.

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Net Income

Our net income for three-month periods ended June 30, 2018 and 2017 was approximately \$10.9 million and \$9.5 million, respectively. The increase in net income was primarily due to increased sales, which were partially offset by a decrease in gross profit as a percentage of sales. Our net income for six-month periods ended June 30, 2018 and 2017 was approximately \$16.2 million and \$24.3 million, respectively. The decrease in net income was primarily related to the gain on bargain purchase of \$11.6 million reported in 2017, which did not recur in 2018, related to the acquisition of the Argon critical care division, which was partially offset by increased sales in the six months ended June 30, 2018 compared to the same period in 2017.

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LIQUIDITY AND CAPITAL RESOURCES

Capital Commitments, Contractual Obligations and Cash Flows

At June 30, 2018 and December 31, 2017, we had cash and cash equivalents of approximately \$43.5 million and \$32.3 million respectively, of which approximately \$41.9 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 June 30, 2018 and December 31, 2017, we had cash and cash equivalents of approximately \$22.9 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 six-month periods ended June 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 June 30, 2018 and December 31, 2017 was approximately \$231.4 million and \$200.5 million, respectively. The increase in working capital as of June 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 June 30, 2018 and December 31, 2017, we had a current ratio of 2.66 to 1 and 2.73 to 1, respectively.

During the six-month period ended June 30, 2018, our inventory balance increased approximately \$14.0 million, from approximately \$155.3 million as of December 31, 2017 to approximately \$169.3 million as of June 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 June 30, 2018 was 2.90, 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 six-month period ended June 30, 2018 was approximately \$138.1 million compared to approximately \$57.6 million for the six-month period

June 30, 2018 was approximately \$138.1 million compared to approximately \$57.6 million for the six-month period ended June 30, 2017, an increase of approximately \$80.5 million. The increase in net cash provided from financing activities was primarily the result of additional borrowings in 2018 to fund the acquisition of assets from BD, NinePoint and DirectACCESS, partially offset by a decrease in proceeds from the issuance of common stock (as no public equity offering was undertaken in the six-month period ended June 30, 2018).

On March 14, 2018, we renewed our loan agreement with HSBC Bank USA, National Association ("HSBC Bank") whereby HSBC Bank agreed to provide us with a loan in the amount of approximately \$7.0 million. The loan matures on July 10, 2018, with an extension available at our option, subject to certain conditions. The loan agreement bears interest at the three-month LIBOR plus 1.0%, which resets quarterly. The loan is secured by assets equal to the currently outstanding loan balance. The loan contains covenants, representations and warranties and other terms customary for loans of this nature. As of June 30, 2018, our interest rate on the loan was a variable rate of 3.26%.

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

Maximum Consolidated Total Leverage Ratio (as

- (1) defined in the Second Amended Credit Agreement) as of any fiscal quarter end.
 - Minimum ratio of Consolidated EBITDA (as defined in the Second Amended Credit Agreement and adjusted
- (2) for certain expenditures) to Consolidated Fixed Charges (as defined in the Second Amended Credit Agreement) for any period of four consecutive fiscal quarters.
 - Minimum level of Consolidated Net Income (as
- (3) defined in the Second Amended Credit Agreement) for certain periods, and subject to certain adjustments. Maximum level of the aggregate amount of all Facility
- (4) 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 June 30, 2018, we believe we were in compliance with all covenants set forth in the Second Amended Credit Agreement.

As of June 30, 2018, we had outstanding borrowings of approximately \$407.0 million under the Second Amended Credit Agreement (an increase in long-term debt of approximately \$132.6 million from December 31, 2017, which was principally due to our acquisition of assets from BD, NinePoint and DirectACCESS), with available borrowings of approximately \$47.8 million, based on the leverage ratio required pursuant to the Second Amended Credit Agreement. Our interest rate as of June 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 3.84% on \$232.0 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 16 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 six-month period ended June 30, 2018 was approximately \$162.5 million compared to approximately \$73.7 million for the six-month period ended June 30, 2017, an increase of approximately \$88.8 million. This increase was primarily a result of an increase

of approximately \$63.8 million in net cash paid for acquisitions during the six months ended June 30, 2018, compared to the six months ended June 30, 2017 (see Note 5 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report), combined with a \$13.8 million increase in capital expenditures for property and equipment. Capital expenditures for property and equipment were approximately \$31.6 million and \$17.8 million for the six-month periods ended June 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.

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,

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results of operations, liquidity, capital expenditures or capital resources that are material to investors. As of June 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 June 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 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

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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 2017, which was completed during the third quarter of 2017, 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 fourth quarter of 2017, we compared the carrying value of the amortizing intangible assets acquired in our July 2015 acquisition of certain assets from Distal Access, 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 Distal Access 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 Distal Access 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 Distal Access of approximately \$809,000 during the fourth quarter of 2017.

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.

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Item 3. QUANTITATIVE AND QUALITATIVE DICSLOSURES 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 six-month period ended June 30, 2018, a portion of our net sales (approximately \$143.4 million, representing approximately 33.5% 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% 10%

Strengthe Wing kening

Impact to Operating Income of:

EUR \$4,300 \$ (4,300) CNY \$(5,800)\$ 5,800

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During the three and six months ended June 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):

Three Months Ended
June 30, 2018

Six Months Ended
June 30, 2018

Amounts Amounts

	Increase/(Decreas Increas	t e) se/(Decrease)	Increase/(Decrea Increa	nt se) ase/(Decrease)
Net Sales	\$ 3,645	1.6	%	\$ 8,798	2.1	%
Cost of Sales	\$ 2,521	2.1	%	\$ 4,596	2.0	%
Gross Profit (1)	\$ 1,124	1.1	%	\$ 4,202	2.3	%

⁽¹⁾ Represents approximately 22 basis points decrease and 8 basis points increase in gross margin percentage for the three and six months ended June 30, 2018, respectively

The impact to sales for the three and six months ended June 30, 2018 was primarily a result of favorable impacts due to sales denominated in EUR, CNY, and GBP. 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 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 June 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 2,410 **Swiss Franc** CHF 1,158 Chinese Renminbi CNY 66,000 Danish Krone DKK 11,650 Euro **EUR** 12,870 **British Pound** GBP 2,975 Mexican Peso MXN 94,275 Swedish Krona SEK 13,830

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 June 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):

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Currency	Symbol	Forward Notional Amount
Australian Dollar	AUD	8,400
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

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 June 30, 2018, we had outstanding borrowings of approximately \$407.0 million under the Second Amended Credit Agreement, an increase in long-term debt of approximately \$132.6 million from December 31, 2017, which was principally due to our acquisition of assets from BD, NinePoint and DirectACCESS. 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 June 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 \$2.3 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 June 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 June 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. As we grow through acquisitions and, at any given time, we may be considering a number of potential further acquisitions and strategic transactions, certain of which may also be significant. As we grow through acquisitions, we face the additional challenges of integrating the operations, culture, information management systems and other characteristics of the acquired entity with our own. Efforts to integrate future acquisitions may be hampered by delays, the loss of certain employees, suppliers or customers, proceedings resulting from employment terminations, culture clashes, unbudgeted costs, and other issues, which may occur at levels that are more severe or prolonged than anticipated. Additionally, past and future acquisitions may increase the risks of competition we face by, among other things, extending our operations into industry segments and product lines where we have few existing customers or qualified sales personnel and limited expertise. For example, although we acquired certain tunneled home drainage catheter and soft tissue core needle biopsy products from BD in February 2018, BD retained other products that directly compete with the products we acquired. As BD is a larger company with a more well-established market presence in such product lines, we may be unable to realize expected benefits from the acquisition in the timeframe anticipated or at all.

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

transactions may have an adverse effect on our business, operations or financial condition.

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

The marketing clearances and approvals from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific uses. We are prohibited from marketing or promoting any uncleared or unapproved use of our product. However, physicians may use these products in ways or circumstances other than those strictly within the scope of the regulatory approval or clearance. The use of our products for unauthorized purposes could arise from our sales personnel or distributors violating our policies by providing information or recommendations about such unauthorized uses. Consequently, claims may be asserted by the FDA or other enforcement agencies that we are not in compliance with applicable laws or regulations or have improperly

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

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

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

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

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

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

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

develop would result in delayed or no realization of revenue from such product enhancements or new products and in substantial additional costs, which could decrease our profitability.

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

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

Our products are subject to medical device reporting regulations, which require us to report to the FDA any information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or

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

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

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

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

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

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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

Second

Amended and

3.1 Restated

Articles of Incorporation

<u>(1)</u>

Third Amended

3.2 <u>and Restated</u>

Bylaws (1)

Merit Medical

Systems, Inc.

10.1 $\frac{2018}{7}$

Long-Term

Incentive Plan

<u>(2)</u>

Indemnification

Agreement by

and between

10.2 Merit Medical

Systems, Inc.

and Raul Parra,

dated August 1.

<u>2018</u>

Employment

Agreement by

and between

10.3 Merit Medical

Systems, Inc.

and Raul Parra,

dated August 1,

2018

Certification of

Chief Executive

Officer pursuant

31.1 <u>to Section 302</u>

of the

Sarbanes-Oxley

Act of 2002

Certification of **Chief Financial** Officer pursuant 31.2 to Section 302 of the Sarbanes-Oxley Act of 2002 Certification of **Chief Executive** Officer pursuant 32.1 to Section 906 of the Sarbanes-Oxley Act of 2002 Certification of **Chief Financial** Officer pursuant 32.2 to Section 906 of the Sarbanes-Oxley Act of 2002 101 The following financial information from the quarterly report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended June 30, 2018, formatted in XBRL (eXtensible **Business** Reporting Language): (i) Consolidated Statements of Income, (ii) Consolidated Balance Sheets, (iii) Consolidated Statements of Comprehensive

Income, (iv)

Consolidated Statements of Cash Flows, and (v) Condensed Notes to the Consolidated Financial

Statements

- (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: August 9, 2018 By:/s/FRED P. LAMPROPOULOS

Fred P. Lampropoulos, President and

Chief Executive Officer

Date: August 9, 2018 By:/s/ RAUL PARRA

Raul Parra

Chief Financial Officer and Treasurer