

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended: September 30, 2019
or

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

For the transition period from: to

Commission File No.: 001-34634

ICU MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

33-0022692

(I.R.S. Employer
Identification No.)

951 Calle Amanecer, San Clemente, California

(Address of principal executive offices)

92673

(Zip Code)

(949) 366-2183

(Registrant's telephone number including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, par value \$0.10 per share	ICUI	The Nasdaq Stock Market LLC (Global Select Market)

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

Class	Outstanding at October 31, 2019
Common	20,673,333

ICU MEDICAL, INC. AND SUBSIDIARIES
Form 10-Q
September 30, 2019

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PART I - FINANCIAL INFORMATION
Item 1. Financial Statements (Unaudited)

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value data)

	September 30, 2019	December 31, 2018
	(Unaudited)	(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 315,949	\$ 344,781
Short-term investment securities	20,845	37,329
TOTAL CASH, CASH EQUIVALENTS AND INVESTMENT SECURITIES	336,794	382,110
Accounts receivable, net of allowance for doubtful accounts of \$13,439 at September 30, 2019 and \$5,768 at December 31, 2018	210,449	176,298
Inventories	343,715	311,163
Prepaid income tax	19,724	11,348
Prepaid expenses and other current assets	33,807	46,117
TOTAL CURRENT ASSETS	944,489	927,036
PROPERTY AND EQUIPMENT, net	444,087	432,641
OPERATING LEASE RIGHT-OF-USE ASSETS	35,787	—
LONG-TERM INVESTMENT SECURITIES	—	2,025
GOODWILL	11,019	11,195
INTANGIBLE ASSETS, net	131,644	133,421
DEFERRED INCOME TAXES	23,242	38,654
OTHER ASSETS	47,516	40,419
TOTAL ASSETS	\$ 1,637,784	\$ 1,585,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 125,355	\$ 120,469
Accrued liabilities	130,056	128,820
TOTAL CURRENT LIABILITIES	255,411	249,289
CONTINGENT EARN-OUT LIABILITY	—	47,400
OTHER LONG-TERM LIABILITIES	37,614	20,592
DEFERRED INCOME TAXES	690	721
INCOME TAX LIABILITY	3,734	3,734
COMMITMENTS AND CONTINGENCIES (Note 18)	—	—
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, \$1.00 par value Authorized—500 shares; Issued and outstanding— none	—	—
Common stock, \$0.10 par value — Authorized, 80,000 shares; Issued and outstanding 20,671 shares at September 30, 2019, Issued 20,492 shares at December 31, 2018 and outstanding 20,491 shares at December 31, 2018	2,067	2,049
Additional paid-in capital	659,709	657,899
Treasury stock, at cost	—	(95)
Retained earnings	701,141	620,747
Accumulated other comprehensive loss	(22,582)	(16,945)
TOTAL STOCKHOLDERS' EQUITY	1,340,335	1,263,655
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,637,784	\$ 1,585,391

(1) December 31, 2018 balances were derived from audited consolidated financial statements.

The accompanying notes are an integral part of these condensed consolidated financial statements.

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
TOTAL REVENUES	\$ 307,471	\$ 327,169	\$ 950,685	\$ 1,059,662
COST OF GOODS SOLD	188,919	192,582	592,961	624,274
GROSS PROFIT	118,552	134,587	357,724	435,388
OPERATING EXPENSES:				
Selling, general and administrative	65,876	76,640	206,333	243,471
Research and development	12,002	13,181	36,024	39,342
Restructuring, strategic transaction and integration	7,975	24,012	69,408	64,271
Change in fair value of contingent earn-out	(200)	18,500	(47,400)	20,500
Contract settlement	—	—	3,822	28,917
TOTAL OPERATING EXPENSES	85,653	132,333	268,187	396,501
INCOME FROM OPERATIONS	32,899	2,254	89,537	38,887
INTEREST EXPENSE	(139)	(283)	(411)	(548)
OTHER (EXPENSE) INCOME, net	(10)	(534)	4,660	(3,482)
INCOME BEFORE INCOME TAXES	32,750	1,437	93,786	34,857
(PROVISION) BENEFIT FOR INCOME TAXES	(6,187)	(1,218)	(13,392)	1,291
NET INCOME	\$ 26,563	\$ 219	\$ 80,394	\$ 36,148
NET INCOME PER SHARE				
Basic	\$ 1.29	\$ 0.01	\$ 3.90	\$ 1.78
Diluted	\$ 1.24	\$ 0.01	\$ 3.73	\$ 1.67
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	20,666	20,474	20,607	20,362
Diluted	21,487	21,633	21,556	21,588

The accompanying notes are an integral part of these condensed consolidated financial statements.

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (Unaudited)
(In thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
NET INCOME	\$ 26,563	\$ 219	\$ 80,394	\$ 36,148
Other comprehensive income (loss), net of tax:				
Cash flow hedge adjustments, net of taxes of \$118 and (\$372) for the three months ended September 30, 2019 and 2018, respectively, and (\$204) and (\$376) for the nine months ended September 30, 2019 and 2018, respectively	(375)	1,178	644	1,192
Foreign currency translation adjustment, net of taxes of \$0 for all periods	(7,533)	(5,415)	(6,287)	(7,705)
Other adjustments, net of taxes of \$0 for all periods	—	6	6	11
Other comprehensive loss, net of taxes	(7,908)	(4,231)	(5,637)	(6,502)
TOTAL COMPREHENSIVE INCOME (LOSS)	\$ 18,655	\$ (4,012)	\$ 74,757	\$ 29,646

The accompanying notes are an integral part of these condensed consolidated financial statements.

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated	Total
	Shares	Amount				Other Comprehensive Loss	
Balance, January 1, 2019	20,492	\$ 2,049	\$ 657,899	\$ (95)	\$ 620,747	\$ (16,945)	\$1,263,655
Issuance of restricted stock and exercise of stock options	254	18	(4,289)	5,196	—	—	925
Tax withholding payments related to net share settlement of equity awards	(78)	—	—	(18,157)	—	—	(18,157)
Stock compensation	—	—	6,209	—	—	—	6,209
Other comprehensive loss, net of tax	—	—	—	—	—	(936)	(936)
Net income	—	—	—	—	30,998	—	30,998
Balance, March 31, 2019	20,668	\$ 2,067	\$ 659,819	\$ (13,056)	\$ 651,745	\$ (17,881)	\$1,282,694
Issuance of restricted stock and exercise of stock options	—	—	(8,505)	11,514	—	—	3,009
Tax withholding payments related to net share settlement of equity awards	—	—	—	(108)	—	—	(108)
Stock compensation	—	—	6,229	—	—	—	6,229
Other comprehensive income, net of tax	—	—	—	—	—	3,207	3,207
Net income	—	—	—	—	22,833	—	22,833
Balance, June 30, 2019	20,668	\$ 2,067	\$ 657,543	\$ (1,650)	\$ 674,578	\$ (14,674)	\$1,317,864
Issuance of restricted stock and exercise of stock options	4	—	(1,556)	1,863	—	—	307
Tax withholding payments related to net share settlement of equity awards	(1)	—	—	(213)	—	—	(213)
Stock compensation	—	—	3,722	—	—	—	3,722
Other comprehensive loss, net of tax	—	—	—	—	—	(7,908)	(7,908)
Net income	—	—	—	—	26,563	—	26,563
Balance, September 30, 2019	20,671	\$ 2,067	\$ 659,709	\$ —	\$ 701,141	\$ (22,582)	\$1,340,335

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) - CONTINUED

(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive (Loss) Income		Total
	Shares	Amount						
Balance, January 1, 2018	20,210	\$ 2,021	\$ 625,568	\$ —	\$ 585,624	\$ (14,959)	\$1,198,254	
Cumulative effect of accounting change	—	—	—	—	6,330	—	6,330	
Issuance of restricted stock and exercise of stock options	130	11	982	2,162	—	—	3,155	
Tax withholding payments related to net share settlement of equity awards	(23)	—	—	(5,338)	—	—	(5,338)	
Stock compensation	—	—	5,462	—	—	—	5,462	
Other comprehensive income, net of tax	—	—	—	—	—	17,213	17,213	
Net income	—	—	—	—	4,875	—	4,875	
Balance, March 31, 2018	20,317	\$ 2,032	\$ 632,012	\$ (3,176)	\$ 596,829	\$ 2,254	\$1,229,951	
Issuance of restricted stock and exercise of stock options	143	14	6,080	3,288	—	—	9,382	
Tax withholding payments related to net share settlement of equity awards	—	—	—	(132)	—	—	(132)	
Stock compensation	—	—	6,297	—	—	—	6,297	
Other comprehensive loss, net of tax	—	—	—	—	—	(19,484)	(19,484)	
Net income	—	—	—	—	31,054	—	31,054	
Balance, June 30, 2018	20,460	\$ 2,046	\$ 644,389	\$ (20)	\$ 627,883	\$ (17,230)	\$1,257,068	
Issuance of restricted stock and exercise of stock options	31	3	1,130	541	—	—	1,674	
Tax withholding payments related to net share settlement of equity awards	(2)	—	—	(649)	—	—	(649)	
Stock compensation	—	—	6,233	—	—	—	6,233	
Other comprehensive loss, net of tax	—	—	—	—	—	(4,231)	(4,231)	
Net income	—	—	—	—	219	—	219	
Balance, September 30, 2018	20,489	\$ 2,049	\$ 651,752	\$ (128)	\$ 628,102	\$ (21,461)	\$1,260,314	

ICU MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 80,394	\$ 36,148
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	57,025	55,069
Amortization of right-of-use assets	6,149	—
Provision for doubtful accounts	7,839	638
Provision for warranty and returns	1,277	1,817
Stock compensation	16,161	17,992
Loss on disposal of property and equipment and other assets	13,350	760
Bond premium amortization	103	313
Debt issuance costs amortization	216	216
Change in fair value of contingent earn-out	(47,400)	20,500
Impairment of assets held for sale	—	269
Write-off of acquired intangible	—	5,000
Usage of spare parts	20,044	6,999
Other	1,757	2,100
Changes in operating assets and liabilities:		
Accounts receivable	(32,484)	(38,957)
Inventories	(30,924)	12,201
Prepaid expenses and other assets	8,815	(506)
Related-party receivables	—	31,004
Other assets	(29,494)	(8,319)
Accounts payable	(3,038)	(2,094)
Accrued liabilities	(23,214)	(18,509)
Income taxes, including excess tax benefits and deferred income taxes	6,478	(12,359)
Net cash provided by operating activities	53,054	110,282
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(73,253)	(75,057)
Proceeds from sale of assets held-for-sale, net	—	13,000
Proceeds from sale of asset	19	—
Business acquisitions, net of cash acquired	(4,600)	(1,300)
Intangible asset additions	(6,461)	(5,375)
Purchases of investment securities	(17,994)	(30,495)
Proceeds from sale of investment securities	36,400	14,940
Net cash used in investing activities	(65,889)	(84,287)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	4,240	14,211
Tax withholding payments related to net share settlement of equity awards	(18,478)	(6,119)
Net cash (used in) provided by financing activities	(14,238)	8,092
Effect of exchange rate changes on cash	(1,759)	(5,343)
NET (DECREASE) INCREASE CASH AND CASH EQUIVALENTS	(28,832)	28,744
CASH AND CASH EQUIVALENTS, beginning of period	344,781	290,072
CASH AND CASH EQUIVALENTS, end of period	\$ 315,949	\$ 318,816

The accompanying notes are an integral part of these condensed consolidated financial statements.

ICU MEDICAL, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) - CONTINUED**

(In thousands)

	Nine months ended September 30,	
	2019	2018
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:		
Accounts payable for property and equipment	\$ 11,365	\$ 1,184

The accompanying notes are an integral part of these consolidated financial statements.

Note 1: Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S.") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and reflect all adjustments, consisting of only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated results for the interim periods presented. Results for the interim period are not necessarily indicative of results for the full year. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Annual Report on Form 10-K of ICU Medical, Inc., ("ICU") a Delaware corporation, filed with the SEC for the year ended December 31, 2018.

We are engaged in the development, manufacturing and sale of innovative medical products used in vascular therapy, and critical care applications. We sell the majority of our products through our direct sales force and through independent distributors throughout the U. S. and internationally. Additionally, we sell our products on an original equipment manufacturer basis to other medical device manufacturers. All subsidiaries are wholly owned and are included in the condensed consolidated financial statements. All intercompany balances and transactions have been eliminated.

Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year. These reclassifications had no impact on net income, stockholders' equity or cash flows as previously reported. The reclassifications included reporting foreign exchange gains and losses in other income (expense), net, and removing them from selling, general and administrative expenses. We reclassified related-party receivables to prepaid expenses and other current assets for the current year's presentation, as Pfizer, Inc. ("Pfizer") had sold all of its shares of our ICU common stock as of December 31, 2018, thereby ending its related-party relationship with us. We reclassified operating cash flows due to the purchase and usage of spare parts. The operating cash flows due to the usage of spare parts are included as an adjustment to reconcile net income to net cash provided by operating activities and the purchase of spare parts are presented as cash outflows in operating assets and liabilities-other assets.

Note 2: New Accounting Pronouncements

Recently Adopted Accounting Standards

In February 2016, the FASB issued Accounting Standard Update ("ASU") No. 2016-02, Leases (Topic 842). The amendments in this update require an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on classification as finance or operating lease. The amendments also require certain quantitative and qualitative disclosures about leasing arrangements. The updated guidance required a modified retrospective adoption. In July 2018, the FASB issued ASU No. 2018-11, Targeted Improvements. The amendments in this update provide entities with an additional (and optional) transition method to adopt the new lease requirements by allowing entities to initially apply the requirements by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The amendments in this update also provided lessors with a practical expedient, by class of underlying asset, to not separate nonlease components from the associated lease contract. This expedient is limited to circumstances in which the nonlease components otherwise would be accounted for under the new revenue guidance and both (1) the timing and pattern of transfer are the same for the nonlease components and associated lease component and (2) the lease component, if accounted for separately, would be classified as an operating lease. If the lessor uses this practical expedient they would account for the lease contract in accordance with Topic 606 if the nonlease component is the predominant component otherwise, the lessor should account for the combined component as an operating lease in accordance with Topic 842. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. This ASU clarifies certain language in ASU 2016-02 and corrects certain references and inconsistencies. We adopted these standards effective January 1, 2019 (see Note 5: Leases for a discussion of the impact and required disclosures).

In January 2017, the FASB issued ASU No. 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The amendments in this update remove the second step of the impairment test. An entity will apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The new guidance does not amend the optional qualitative assessment of goodwill impairment. The amendments in ASU 2017-04 are effective for the annual or interim impairment test in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

annual goodwill impairment tests performed on testing dates after January 1, 2017. We early adopted this ASU effective April 1, 2019, which had no impact on our consolidated financial statements or related footnote disclosures. We adopted this ASU early ahead of our annual impairment test to reduce the complexity of the quantitative test if necessary.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal use software license. Costs to develop or obtain internal-use software that cannot be capitalized under subtopic 350-40, such as training costs and certain data conversion costs, also cannot be capitalized for a hosting arrangement that is a service contract. Therefore, an entity in a hosting arrangement that is a service contract determines which project stage (that is, preliminary project stage, application development stage, or post-implementation stage) an implementation activity relates to. Costs for implementation activities in the application development stage are capitalized depending on the nature of the costs, while costs incurred during the preliminary project and post-implementation stages are expensed as the activities are performed. The amendments in this update require the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The amendments in this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements in Topic 820. The amendments remove from disclosure: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. The amendments also made the following disclosure modifications: for investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly; and the amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date. The amendments also added the following disclosure requirements: the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. The amendments in ASU 2018-02 are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update amends the FASB's guidance on the impairment of financial instruments by requiring timelier recording of credit losses on loans and other financial instruments. The ASU adds an impairment model that is based on expected losses rather than incurred losses. The ASU also amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. In April 2019, the FASB issued ASU No. 2019-04 - Codification Improvements to Topic 326, Financial Instruments - Credit Losses and in May 2019, the FASB issued ASU No. 2019-05, Financial Instruments-Credit Losses to Topic 326, Financial Instruments - Targeted Transition Relief. ASU 2019-04 clarifies and corrects certain areas of the Codification and ASU 2019-05 provides entities with an option to irrevocably elect the fair value option in Subtopic 825-10, Financial Instruments—Overall, applied on an instrument-by-instrument basis for eligible instruments, upon adoption of Topic 326. The amendments in these updates will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted as of the fiscal years beginning after December 15, 2018. The updated guidance requires a modified retrospective adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

Note 3: Restructuring, Strategic Transaction and Integration

Restructuring and strategic transaction and integration expenses were \$8.0 million and \$69.4 million for the three and nine months ended September 30, 2019, respectively, as compared to \$24.0 million and \$64.3 million for the three and nine months ended September 30, 2018, respectively.

Restructuring

During the three and nine months ended September 30, 2019, restructuring charges were \$0.8 million and \$8.4 million, respectively, primarily related to severance and facility closure costs. These charges are primarily related to a one-time charge to move our U.S. pump service depot to our existing Salt Lake City facility and other plant restructuring. Restructuring charges are included in the restructuring, strategic transaction and integration line item in our condensed consolidated statement of operations.

During the year ended December 31, 2015, we incurred restructuring charges related to an agreement with Dr. Lopez, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement. The buy-out, including payroll taxes, is paid in equal monthly installments until December 2020.

The following table summarizes the details of changes in our restructuring-related accrual for the period ended September 30, 2019 (in thousands):

	<u>Accrued Balance January 1, 2019</u>	<u>Charges Incurred</u>	<u>Payments</u>	<u>Accrued Balance September 30, 2019</u>
Severance pay and benefits	\$ 677	\$ 5,349	\$ (1,900)	\$ 4,126
Employment agreement buyout	739	—	(279)	460
Facility closure expenses	—	3,095	(595)	2,500
	<u>\$ 1,416</u>	<u>\$ 8,444</u>	<u>\$ (2,774)</u>	<u>\$ 7,086</u>

Strategic transaction and integration expenses

We incurred and expensed \$7.2 million and \$61.0 million in strategic transaction and integration expenses during the three and nine months ended September 30, 2019, respectively, as compared to \$23.5 million and \$61.3 million during the three and nine months ended September 30, 2018, respectively. The strategic transaction and integration expenses during the three months ended September 30, 2019 and the three and nine months ended September 30, 2018 were primarily related to the integration of the Hospira Infusion Systems ("HIS") business acquired in 2017 from Pfizer. The nine months ended September 30, 2019 also included a one-time strategic supply chain restructuring charge of \$22.1 million, which reduces our contracted commitments to our third party manufacturer and charges related to our Pfizer separation costs and clean-up, which included a \$12.7 million non-cash write-off of related assets.

Note 4: Revenue

Our primary product lines are Infusion Consumables, IV Solutions, Infusion Systems and Critical Care. The vast majority of our sales of these products are made on a stand-alone basis to hospitals and distributors. Revenue is typically recognized upon transfer of control of the products, which we deem to be at point of shipment.

Payment is typically due in full within 30 days of delivery or the start of the contract term. Revenue is recorded in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We offer certain volume-based rebates to our distribution customers, which we record as variable consideration when calculating the transaction price. Rebates are offered on both a fixed and tiered/variable basis. In both cases, we use information available at the time and our historical experience with each customer to estimate the most likely rebate amount. We also provide chargebacks to distributors that sell to end-customers at prices determined under a contract between us and the end-customer. We use information available at the time and our historical experience to estimate and record provisions for chargebacks.

We also warrant products against defects and have a policy permitting the return of defective products, for which we accrue and expense at the time of sale using information available at that time and our historical experience. We also provide

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for extended service-type warranties, which we consider to be separate performance obligations. We allocate a portion of the transaction price to the extended service-type warranty based on its estimated relative selling price, and recognize revenue over the period the warranty service is provided.

Revenue disaggregated

The following table represents our revenues disaggregated by geography (in thousands):

Geography	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Europe, the Middle East and Africa	\$ 31,474	\$ 30,759	\$ 96,830	\$ 104,150
Other Foreign	53,398	51,569	156,353	154,278
Total Foreign	84,872	82,328	253,183	258,428
United States	222,599	244,841	697,502	801,234
Total Revenues	\$ 307,471	\$ 327,169	\$ 950,685	\$ 1,059,662

The following table represents our revenues disaggregated by product (in thousands):

Product line	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Infusion Consumables	\$ 119,745	\$ 117,797	\$ 357,994	\$ 361,490
IV Solutions	98,159	114,433	313,976	394,198
Infusion Systems	78,932	81,456	244,523	263,271
Critical Care	10,635	13,483	34,192	40,703
Total Revenues	\$ 307,471	\$ 327,169	\$ 950,685	\$ 1,059,662

Contract balances

The following table presents our changes in the contract balances for the nine months ended September 30, 2019 and 2018 (in thousands):

	Contract Liabilities
Beginning balance, January 1, 2019	\$ (4,282)
Equipment revenue recognized	3,619
Equipment revenue deferred due to implementation	(6,869)
Software revenue recognized	2,955
Software revenue deferred due to implementation	(3,115)
Ending balance, September 30, 2019	<u>\$ (7,692)</u>
Beginning balance, January 1, 2018	\$ (7,066)
Equipment revenue recognized	3,136
Equipment revenue deferred due to implementation	(4,086)
Software revenue recognized	5,649
Software revenue deferred due to implementation	(5,507)
Ending balance, September 30, 2018	<u>\$ (7,874)</u>

As of September 30, 2019, revenue from remaining performance obligations related to implementation of software and equipment is \$6.3 million. We expect to recognize substantially all of this revenue within the next three months. Revenue from

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

remaining performance obligations related to annual software licenses is \$1.4 million. We expect to recognize substantially all of this revenue over the next twelve months.

Note 5: Leases

Adoption of ASC Topic 842, "Lease Accounting"

We adopted ASU No. 2016-02, Leases (ASC Topic 842), effective January 1, 2019 on a modified retrospective transition method through a cumulative-effect adjustment at the beginning of the first quarter of 2019. We elected the 'package of practical expedients', which permitted us not to reassess our prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we did not recognize right-of-use ("ROU") assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Furthermore, we elected the practical expedient to not separate lease and non-lease components for all of our leases, non-lease components are primarily common area maintenance charges that we combine with the lease component when applying this ASU.

The impact of adopting this standard was the recognition of ROU assets and lease liabilities for our operating leases of \$40.4 million as of January 1, 2019. The adoption of ASC 842 did not have a material impact on our consolidated earnings and had no impact on our cash flows.

Leases

We determine if an arrangement is a lease at inception. Most operating leases with a term greater than one year are included in operating lease ROU assets, accrued liabilities, and other long-term liabilities on our condensed consolidated balance sheets.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Most of our leases do not provide an implicit rate, therefore we use our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term based on the information available at commencement date. The operating lease ROU asset excludes lease incentives and initial direct costs incurred. Our lease terms include options to extend when it is reasonably certain that we will exercise that option. All of our operating leases have stated lease payments, which may include fixed rental increases. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We have operating leases for corporate offices, sales and support offices, device service centers and certain equipment. Our leases have original lease terms of one year to fifteen years, some of which include options to extend the leases for up to an additional five years. For all of our leases, we do not include optional periods of extension in our current lease terms for the exercise of options to extend is not reasonably certain.

The following table presents the components of our lease cost (in thousands):

	For the three months ended September 30, 2019	For the nine months ended September 30, 2019
Operating lease cost	\$ 2,996	\$ 7,528
Short-term lease cost	49	229
Total lease cost	\$ 3,045	\$ 7,757

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents the supplemental cash flow information related to our leases (in thousands):

	For the nine months ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 7,161
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	\$ 2,495

The following table presents the supplemental balance sheet information related to our leases (in thousands, except lease term and discount rate):

	As of September 30, 2019
Operating leases	
Operating lease right-of-use assets	\$ 35,787
Accrued liabilities	\$ 7,150
Other long-term liabilities	29,791
Total operating lease liabilities	\$ 36,941
Weighted Average Remaining Lease Term	
Operating leases	6 years
Weighted Average Discount Rate	
Operating leases	5.57%

As of September 30, 2019, the maturities of our lease liabilities for each of the next five years is approximately (in thousands):

	Operating Leases
Remainder of 2019	\$ 2,169
2020	8,409
2021	7,060
2022	6,470
2023	6,118
Thereafter	13,569
Total Lease Payments	43,795
Less imputed interest	(6,854)
Total	\$ 36,941

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2018, the maturities of our operating lease liabilities for each of the next five years were approximately (in thousands):

	Operating Leases	
2019	\$	8,326
2020		8,572
2021		6,489
2022		5,914
2023		5,615
Thereafter		13,235
Total Lease Payments⁽¹⁾	\$	48,151

⁽¹⁾The lease payment maturities as of December 31, 2018 are not calculated at present value.

During the third quarter 2019, we signed a ten-year lease for a 610,806 square foot warehouse. The commencement of the lease is not expected until the first quarter of 2020 subject to the completion of landlord buildouts which will make the space available for use. Over the ten-year lease term, we expect the lease payments to total at least \$21.8 million.

Note 6: Net Income Per Share

Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period plus dilutive securities. Dilutive securities include outstanding common stock options and unvested restricted stock units, less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive, where their exercise price exceeds the average market price of the common stock are not included in the treasury stock method calculation. There were 20,116 and 18 anti-dilutive securities for the three months ended September 30, 2019 and 2018, respectively. There were 9,375 and 3,694 anti-dilutive securities for the nine months ended September 30, 2019 and 2018, respectively.

The following table presents the calculation of net earnings per common share ("EPS") — basic and diluted (in thousands, except per share data):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net income	\$ 26,563	\$ 219	\$ 80,394	\$ 36,148
Weighted-average number of common shares outstanding (for basic calculation)	20,666	20,474	20,607	20,362
Dilutive securities	821	1,159	949	1,226
Weighted-average common and common equivalent shares outstanding (for diluted calculation)	21,487	21,633	21,556	21,588
EPS — basic	\$ 1.29	\$ 0.01	\$ 3.90	\$ 1.78
EPS — diluted	\$ 1.24	\$ 0.01	\$ 3.73	\$ 1.67

Note 7: Derivatives and Hedging Activities

Hedge Accounting and Hedging Program

The purpose of our hedging program is to manage the foreign currency exchange rate risk on forecasted expenses denominated in currencies other than the functional currency of the operating unit. We do not issue derivatives for trading or speculative purposes.

In May 2017, we entered into a two-year cross-currency par forward contract to hedge a portion of our Mexico forecasted expenses denominated in Pesos ("MXN"). To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

flows on hedged transactions. The par forward contract is designated and qualifies as a cash flow hedge. Our derivative instrument is recorded at fair value on the condensed consolidated balance sheets and is classified based on the instrument's maturity date. We record changes in the intrinsic value of the effective portion of the gain or loss on the derivative instrument as a component of Other Comprehensive Income and we reclassify that gain or loss into earnings in the same line item associated with the forecasted transaction and in the same period during which the hedged transaction affects earnings. This contract matured May 1, 2019. This derivative instrument had a fixed forward rate of 20.01MXN/USD over the term of the contract.

In January 2018, we entered into an additional six-month cross-currency par forward contract that extends our current hedge of a portion of our Mexico forecasted expenses denominated in MXN. The total notional amount of this outstanding derivative as of September 30, 2019 was approximately 61.3 million MXN. The term of the six-month contract is May 1, 2019 to November 1, 2019. The derivative instrument matures in equal monthly amounts at a fixed forward rate of 20.43 MXN/USD over the term of the six-month contract.

In November 2018, we entered into a one-year cross-currency par forward contract again extending the hedge of a portion of our Mexico forecasted expenses denominated in MXN. The total notional amount of this outstanding derivative as of September 30, 2019 was approximately 398.0 million MXN. The term of the one-year hedge is November 1, 2019 to November 3, 2020. The derivative instrument matures in equal monthly amounts at a fixed forward rate of 22.109 MXN/USD.

The following table presents the fair values of our derivative instruments included within the Condensed Consolidated Balance Sheet as of September 30, 2019 and December 31, 2018 (in thousands):

	Derivatives		
	Condensed Consolidated Balance Sheet Location	September 30, 2019	December 31, 2018
<i>Derivatives designated as cash flow hedging instruments</i>			
Foreign exchange forward contract:			
	Prepaid expenses and other current assets	\$ 1,300	\$ 187
	Other assets	279	545
Total derivatives designated as cash flow hedging instruments		<u>\$ 1,579</u>	<u>\$ 732</u>

The following table presents the amounts affecting the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Line Item in the Condensed Consolidated Statements of Operations	Three months ended September 30,		Nine months ended September 30,	
		2019	2018	2019	2018
<i>Derivatives designated as cash flow hedging instruments</i>					
Foreign exchange forward contracts	Cost of goods sold	\$ 229	\$ 192	\$ 573	\$ 687

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We recognized the following (losses) gains on our foreign exchange contracts designated as a cash flow hedge (in thousands):

	Amount of (Loss) Gain Recognized in Other Comprehensive Income on Derivatives		Location of Gain Reclassified From Accumulated Other Comprehensive Income into Income	Amount of Gain Reclassified From Accumulated Other Comprehensive Income into Income	
	Three months ended September 30,			Three months ended September 30,	
	2019	2018		2019	2018
Derivatives designated as cash flow hedges:					
Foreign exchange forward contract	\$ (264)	\$ 1,743	Cost of goods sold	\$ 229	\$ 192
Total derivatives designated as cash flow hedging instruments	<u>\$ (264)</u>	<u>\$ 1,743</u>		<u>\$ 229</u>	<u>\$ 192</u>

	Amount of Gain Recognized in Other Comprehensive Income on Derivatives		Location of Gain Reclassified From Accumulated Other Comprehensive Income into Income	Amount of Gain Reclassified From Accumulated Other Comprehensive Income into Income	
	Nine months ended September 30,			Nine months ended September 30,	
	2019	2018		2019	2018
Derivatives designated as cash flow hedges:					
Foreign exchange forward contract	\$ 1,421	\$ 2,256	Cost of goods sold	\$ 573	\$ 687
Total derivatives designated as cash flow hedging instruments	<u>\$ 1,421</u>	<u>\$ 2,256</u>		<u>\$ 573</u>	<u>\$ 687</u>

As of September 30, 2019, we expect approximately \$1.4 million of the deferred gains on the outstanding derivatives in accumulated other comprehensive income to be reclassified to net income during the next 12 months concurrent with the underlying hedged transactions also being reported in net income.

Note 8: Fair Value Measurement

Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. There are three levels of inputs that may be used to measure fair value:

- Level 1: quoted prices in active markets for identical assets or liabilities;
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair values of the assets or liabilities.

In 2017, we acquired HIS from Pfizer, and as a result of the acquisition we recognized an earn-out liability. Pfizer is entitled up to \$225.0 million in cash if certain performance targets for the combined company for the three years ending December 31, 2019 are achieved. The initial value assigned to the contingent consideration was a result of forecasted product demand and operations of our business. The initial fair value of the earn-out was determined by employing a Monte Carlo simulation in a risk neutral framework. The underlying simulated variable was adjusted EBITDA. The adjusted EBITDA

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model includes other assumptions including the market price of risk, which was calculated as the weighted average cost of capital ("WACC") less the long-term risk free-rate. At each reporting date subsequent to the acquisition we re-measured the earn-out using the same methodology above and recognized any changes in value. If the probability of achieving the performance target significantly changes from what we initially anticipated, the change could have a significant impact on our financial statements in the period recognized. Our contingent earn-out liability is separately stated in our condensed consolidated balance sheets.

The following table provides a reconciliation of the Level 3 earn-out liability measured at estimated fair value as of December 31, 2018 to September 30, 2019 (in thousands):

	Earn-out Liability
Accrued balance, January 1, 2019	\$ 47,400
Change in fair value of earn-out (included in income from operations as a separate line item)	(47,400)
Accrued balance, September 30, 2019	<u>\$ —</u>

The fair value of the earn-out at September 30, 2019 changed from the fair value calculated at December 31, 2018 due to a change in the underlying cumulative adjusted EBITDA forecast. As of September 30, 2019, there is a remote probability that we will meet the performance targets necessary for payout of the earn-out, accordingly the liability has been reduced to zero.

The following table provides quantitative information about Level 3 inputs for fair value measurement of our earn-out liability as of December 31, 2018.

Simulation Input	As of December 31, 2018
Adjusted EBITDA Volatility	30.00%
WACC	8.25%
20-year risk free rate	2.87%
Market price of risk	5.24%
Cost of debt	5.25%

The fair value of our investments is estimated using observable market-based inputs such as quoted prices, interest rates and yield curves or Level 2 inputs, which consisted of corporate bonds.

The fair value of our Level 2 forward currency contracts are estimated using observable market inputs such as known notional value amounts, spot and forward exchange rates. These inputs relate to liquid, heavily traded currencies with active markets which are available for the full term of the derivative.

There were no transfers between levels during the nine months ended September 30, 2019.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our assets and liabilities measured at fair value on a recurring basis consisted of the following (Level 1, 2 and 3 inputs as defined above) (in thousands):

	Fair value measurements at September 30, 2019			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Available for sale securities:				
Short-term	\$ 20,845	\$ —	\$ 20,845	\$ —
Long-term	—	—	—	—
Foreign exchange forwards:				
Prepaid expenses and other current assets	1,300	—	1,300	—
Other assets	279	—	279	—
Total Assets	\$ 22,424	\$ —	\$ 22,424	\$ —

	Fair value measurements at December 31, 2018			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Available for sale securities:				
Short-term	\$ 37,329	\$ —	\$ 37,329	\$ —
Long-term	2,025	—	2,025	—
Foreign exchange forwards:				
Prepaid expenses and other current assets	187	—	187	—
Other assets	545	—	545	—
Total Assets	\$ 40,086	\$ —	\$ 40,086	\$ —
Liabilities:				
Earn-out liability	\$ 47,400	\$ —	\$ —	\$ 47,400
Total Liabilities	\$ 47,400	\$ —	\$ —	\$ 47,400

Note 9: Investment Securities

Our investment securities currently consist of short-term and long-term corporate bonds. Our investment securities are considered available-for-sale and are “investment grade” and carried at fair value. Available-for-sale securities are recorded at fair value, and unrealized holding gains and losses are recorded, net of tax, as a component of accumulated other comprehensive income (loss). Unrealized losses on available-for-sale securities are charged against net earnings when a decline in fair value is determined to be other than temporary. Our management reviews several factors to determine whether a loss is other than temporary, such as the length and extent of the fair value decline, the financial condition and near term prospects of the issuer, and for equity investments, our intent and ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. The amortized cost of the debt securities are adjusted for the amortization of premiums computed under the effective interest method. Such amortization is included in investment income in other income on our condensed consolidated statements of operations. There have been no realized gains or losses on their disposal. Realized gains and losses are accounted for on the specific identification method. The scheduled maturities of the debt securities are between 2019 and 2020. All short-term investment securities are callable within one year.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our short and long-term investment securities consisted of the following (in thousands):

	As of September 30, 2019		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	\$ 20,845	\$ —	\$ 20,845
Long-term corporate bonds	—	—	—
Total investment securities	\$ 20,845	\$ —	\$ 20,845

	As of December 31, 2018		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	\$ 37,329	\$ —	\$ 37,329
Long-term corporate bonds	2,025	—	2,025
Total investment securities	\$ 39,354	\$ —	\$ 39,354

Note 10: Prepaid Expenses, Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Deposits	\$ 1,305	\$ 1,087
Other prepaid expenses and receivables	16,597	12,476
Receivables from Pfizer related to HIS business acquisition ⁽¹⁾	—	20,137
Deferred costs	6,366	1,951
Prepaid insurance and property taxes	680	2,666
VAT/GST receivable	4,379	5,072
Deferred tax charge	1,180	1,180
Other	3,300	1,548
	\$ 33,807	\$ 46,117

⁽¹⁾As of December 31, 2018, Pfizer had sold all of its shares of our common stock thereby ending its related-party relationship with us. We reclassified the December 31, 2018 related-party receivable due from Pfizer to prepaid expenses, other current assets for current year presentation purposes.

Note 11: Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined using the first-in, first-out method. Inventory costs consist of those costs directly attributable to products prior to sale including among other things raw material, labor and overhead. Inventories consisted of the following (in thousands)

	September 30, 2019	December 31, 2018
Raw material	\$ 110,954	\$ 104,104
Work in process	47,339	52,909
Finished goods	185,422	154,150
Total inventories	\$ 343,715	\$ 311,163

Note 12: Property and Equipment

Property and equipment consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Machinery and equipment	\$ 213,957	\$ 203,431
Land, building and building improvements	228,960	212,283
Molds	59,749	59,700
Computer equipment and software	82,993	80,420
Furniture and fixtures	7,405	7,409
Instruments placed with customers ⁽¹⁾	70,146	60,757
Construction in progress	85,908	70,864
Total property and equipment, cost	749,118	694,864
Accumulated depreciation	(305,031)	(262,223)
Property and equipment, net	\$ 444,087	\$ 432,641

⁽¹⁾Instruments placed with customers consist of drug-delivery and monitoring systems placed with customers.

Depreciation expense was \$14.8 million and \$44.6 million for the three and nine months ended September 30, 2019, respectively, as compared to \$15.1 million and \$42.8 million for the three and nine months ended September 30, 2018, respectively.

Note 13: Goodwill and Intangible Assets, Net*Goodwill*

The following table presents the changes in the carrying amount of our goodwill (in thousands):

	Total
Balance as of January 1, 2019	\$ 11,195
Currency translation	(176)
Balance as of September 30, 2019	\$ 11,019

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Intangible Assets, Net

Intangible assets, carried at cost less accumulated amortization and amortized on a straight-lined basis, were as follows (in thousands):

	Weighted Average Amortization Life in Years	September 30, 2019		
		Cost	Accumulated Amortization	Net
Patents	10	\$ 21,736	\$ 13,161	\$ 8,575
Customer contracts ⁽¹⁾	12	9,990	5,419	4,571
Non-contractual customer relationships	9	57,602	18,413	39,189
Trademarks	4	425	425	—
Trade name	15	7,450	2,003	5,447
Developed technology	11	82,634	21,082	61,552
Total amortized intangible assets		\$ 179,837	\$ 60,503	\$ 119,334
IPR&D		\$ 12,310		\$ 12,310
Total intangible assets		\$ 192,147	\$ 60,503	\$ 131,644

⁽¹⁾ During the second quarter of 2019, we acquired certain assets from one of our distributors. We recorded \$4.6 million in customer contracts related to that agreement.

	Weighted Average Amortization Life in Years	December 31, 2018		
		Cost	Accumulated Amortization	Net
Patents	10	\$ 19,399	\$ 12,147	\$ 7,252
Customer contracts	9	5,319	5,272	47
Non-contractual customer relationships	9	57,916	13,363	44,553
Trademarks	4	425	425	—
Trade name	15	7,456	1,618	5,838
Developed technology	11	82,857	15,361	67,496
Total amortized intangible assets		\$ 173,372	\$ 48,186	\$ 125,186
IPR&D		\$ 8,235		\$ 8,235
Total intangible assets		\$ 181,607	\$ 48,186	\$ 133,421

Intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. During the three and nine months ended September 30, 2019, intangible asset amortization expense was \$4.4 million and \$12.4 million, respectively, as compared to \$4.1 million and \$12.2 million for the three and nine months ended September 30, 2018, respectively.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2019 estimated annual amortization for our intangible assets for each of the next five years is approximately (in thousands):

Remainder of 2019	\$	4,809
2020		16,669
2021		16,366
2022		16,222
2023		16,073
Thereafter		49,195
Total	\$	119,334

Note 14: Accrued Liabilities and Other Long-Term Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Salaries and benefits	\$ 28,273	\$ 20,538
Incentive compensation	13,026	42,913
Accrued supply chain restructuring costs	23,751	—
Operating lease liability-ST	7,150	—
Accrued product field action	1,705	5,316
Third-party inventory	—	1,089
Consigned inventory	—	1,118
Accrued sales taxes	2,134	2,941
Restructuring accrual	6,996	1,046
Deferred revenue	7,441	3,814
Accrued other taxes	3,253	3,213
Accrued professional fees	7,098	15,996
Legal accrual	621	1,400
Distribution fees	4,578	3,977
Warranties and returns	886	1,124
Accrued freight	12,108	10,953
Contract liabilities-ST	3,045	—
Contract settlement	1,667	2,083
Accrued research and development	—	1,451
Other	6,324	9,848
	\$ 130,056	\$ 128,820

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Other long-term liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Contract liabilities-LT	\$ 3,716	\$ 14,020
Contract settlement	417	1,667
Operating lease liability-LT	29,791	—
Benefits	763	962
Accrued rent	1,669	1,779
Deferred revenue	251	468
Other	1,007	1,696
	<u>\$ 37,614</u>	<u>\$ 20,592</u>

Note 15: Income Taxes

Income taxes were accrued at an estimated effective tax rate of 19% and 14% for the three and nine months ended September 30, 2019, respectively, as compared to 85% and (4)% for the three and nine months ended September 30, 2018, respectively.

The effective tax rate for the three and nine months ended September 30, 2019 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes, global intangible low-taxed income ("GILTI") and tax credits, and by the following discrete tax items recognized during the interim periods:

- Excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the three and nine months ended September 30, 2019 of \$0.3 million and \$7.7 million, respectively.
- The revaluation of the contingent consideration during the nine months ended September 30, 2019 resulted in a tax expense of \$11.4 million.
- The repatriation of certain intellectual property and assets from one of our foreign subsidiaries to the U.S. parent resulted in a net tax benefit of \$3.8 million.
- A return-to-provision adjustment for the year ended December 31, 2018 included a tax expense of \$2.2 million primarily due to changes in estimates for GILTI.

The effective tax rate for the three and nine months ended September 30, 2018 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes and tax credits. The effective tax rate during the three and nine months ended September 30, 2018 included a discrete tax benefit of \$1.6 million and \$12.8 million, respectively, related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. The effective tax rate for the nine months ended September 30, 2018 was also impacted by a contract settlement. The contract settlement resulted in a discrete tax benefit of \$5.7 million.

Note 16: Long-Term Obligations

Five-year Senior Secured Revolving Credit Facility ("Credit Facility")

On November 8, 2017, we entered into a Credit Facility with various lenders for \$150.0 million, with Wells Fargo Bank, N.A. as the administrative agent, swingline lender and issuing lender. As of September 30, 2019, we had no borrowings and \$150.0 million of availability under the Credit Facility. The Credit Facility matures on November 8, 2022.

Debt Covenants

The Credit Facility contains certain financial covenants pertaining to Consolidated Fixed Charge Coverage and Consolidated Total Leverage Ratios. In addition, the Credit Facility has restrictions pertaining to limitations on debt, liens, negative pledges, loans, advances, acquisitions, other investments, dividends, distributions, redemptions, repurchases of equity interests, fundamental changes and asset sales and other dispositions, prepayments, redemptions and purchases of subordinated debt and other junior debt, transactions with affiliates, dividend and payment restrictions affecting subsidiaries, changes in line of business, fiscal year and accounting practices and amendment of organizational documents and junior debt documents.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Consolidated Leverage Ratio is defined as the ratio of Consolidated Total Funded Indebtedness on such date, to Consolidated Adjusted EBITDA, as defined under the Credit Facility Agreement, for the most recently completed four fiscal quarters. The maximum Consolidated Leverage Ratio is not more than 3.00 to 1.00.

The Consolidated Fixed Charge Coverage Ratio is defined as the ratio of: (a) Consolidated Adjusted EBITDA less the sum of (i) capital expenditures, (ii) federal, state, local and foreign income taxes paid in cash and (iii) cash restricted payments made after the closing date, to (b) Consolidated Fixed Charges for the most recently completed four fiscal quarters, calculated on a pro forma basis. The minimum Consolidated Fixed Charge Coverage Ratio is 2.00 to 1.00.

We were in compliance with all financial covenants as of September 30, 2019.

Note 17: Stockholders' Equity

Treasury Stock

In August 2019, our Board of Directors approved a new share purchase plan to purchase up to \$100.0 million of our common stock. This plan replaced our existing plan and has no expiration date. During the nine months ended September 30, 2019, we did not purchase any shares of our common stock under our stock purchase plans. As of September 30, 2019, all of the \$100.0 million available for purchase was remaining under the plan. We are currently limited on share purchases in accordance with the terms and conditions of our Credit Facility (see Note 16: Long-Term Obligations).

For the nine months ended September 30, 2019, we withheld 79,313 shares of our common stock from employee vested restricted stock units in consideration for \$18.5 million in payments made on the employee's behalf for their minimum statutory income tax withholding obligations. Treasury stock is used to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income ("AOCI"), net of tax, were as follows (in thousands):

	Foreign Currency Translation Adjustments	Unrealized Gains on Cash Flow Hedges	Other Adjustments	Total
Balance as of January 1, 2019	\$ (17,682)	\$ 638	\$ 99	\$ (16,945)
Other comprehensive (loss) income before reclassifications	(1,592)	768	6	(818)
Amounts reclassified from AOCI	—	(118)	—	(118)
Other comprehensive (loss) income	(1,592)	650	6	(936)
Balance as of March 31, 2019	\$ (19,274)	\$ 1,288	\$ 105	\$ (17,881)
Other comprehensive income before reclassifications	2,838	513	—	3,351
Amounts reclassified from AOCI	—	(144)	—	(144)
Other comprehensive income	2,838	369	—	3,207
Balance as of June 30, 2019	\$ (16,436)	\$ 1,657	\$ 105	\$ (14,674)
Other comprehensive loss before reclassifications	(7,533)	(201)	—	(7,734)
Amounts reclassified from AOCI	—	(174)	—	(174)
Other comprehensive loss	(7,533)	(375)	—	(7,908)
Balance as of September 30, 2019	\$ (23,969)	\$ 1,282	\$ 105	\$ (22,582)

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Foreign Currency Translation Adjustments	Unrealized Gains on Cash Flow Hedges	Other Adjustments	Total
Balance as of January 1, 2018	\$ (14,578)	\$ (365)	\$ (16)	\$ (14,959)
Other comprehensive income before reclassifications	15,397	1,993	2	17,392
Amounts reclassified from AOCI	—	(179)	—	(179)
Other comprehensive (loss) income	15,397	1,814	2	17,213
Balance as of March 31, 2018	\$ 819	\$ 1,449	\$ (14)	\$ 2,254
Other comprehensive income before reclassifications	(17,687)	(1,602)	3	(19,286)
Amounts reclassified from AOCI	—	(198)	—	(198)
Other comprehensive (loss) income	(17,687)	(1,800)	3	(19,484)
Balance as of June 30, 2018	\$ (16,868)	\$ (351)	\$ (11)	\$ (17,230)
Other comprehensive income before reclassifications	(5,415)	1,323	6	(4,086)
Amounts reclassified from AOCI	—	(145)	—	(145)
Other comprehensive (loss) income	(5,415)	1,178	6	(4,231)
Balance as of September 30, 2018	\$ (22,283)	\$ 827	\$ (5)	\$ (21,461)

Note 18: Commitments and Contingencies

Legal Proceedings

Beginning in November 2016, purported class actions were filed in the U.S. District Court for the Northern District of Illinois against Pfizer, Inc. subsidiaries, Hospira, Inc., Hospira Worldwide, Inc. and certain other defendants relating to the intravenous saline solutions part of the HIS business. Plaintiffs seek to represent classes consisting of all persons and entities in the U.S. who directly purchased intravenous saline solution sold by any of the defendants from January 1, 2013 until the time the defendants' allegedly unlawful conduct ceases. Plaintiffs allege that U.S. manufacturer defendants conspired together to restrict output and artificially fix, raise, maintain and/or stabilize the prices of intravenous saline solution sold throughout the U.S. in violation of federal antitrust laws. Plaintiffs seek treble damages (for themselves and on behalf of the putative classes) and an injunction against defendants for alleged price overcharges for intravenous saline solution in the U.S. since January 1, 2013. On July 5, 2018, the District Court granted defendants' motion to dismiss the operative complaint for failing to state a valid antitrust claim, but allowed the plaintiffs to file a second amended complaint. On September 6, 2018, plaintiffs filed a second amended complaint adding new allegations in support of their conspiracy claims and adding ICU as a defendant. All defendants have filed a motion to dismiss this second amended complaint. Briefing is complete and we are awaiting the Court's ruling. On February 3, 2017, we completed the acquisition of the HIS business from Pfizer. This litigation is the subject of a claim for indemnification against us by Pfizer and a cross-claim for indemnification against Pfizer by us under the HIS stock and asset purchase agreement.

In addition, in August 2015, the New York Attorney General issued a subpoena to Hospira, Inc. requesting that the company provide information regarding certain business practices in the intravenous solutions part of the HIS business. Separately, in April 2017, we received a grand jury subpoena issued by the United States District Court for the Eastern District of Pennsylvania, in connection with an investigation by the U.S. Department of Justice, Antitrust Division. The subpoenas call for production of documents related to the manufacturing, selling, pricing and shortages of intravenous solutions, including saline, as well as communications among market participants regarding these issues. On December 10, 2018, we were informed by the U.S. Department of Justice, Antitrust Division, that their investigation has been closed.

In April 2018, the U.S. Department of Justice issued a HIPAA subpoena to Hospira, Inc., requesting production of documents and records regarding the manufacturing, production, testing, quality and validation of the Sapphire™ infusion pumps, sets and related accessories distributed by the company. We have coordinated with Pfizer to produce the requested records to the Department of Justice.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In March 2018, a dispute with a product partner resulted in a redefinition of our contractual arrangement and in the rights and remedies determined under such arrangement. The resolution of the dispute resulted in a \$28.9 million net charge to the condensed consolidated statement of operations. In addition, during the fourth quarter of 2018, we incurred \$12.7 million in additional contract settlement charges related to this arrangement as a result of the write-off of assets and additional expenses associated with the restructuring of products.

From time to time, we are involved in various legal proceedings, most of which are routine litigation, in the normal course of business. Our management does not believe that the resolution of the unsettled legal proceedings that we are involved with will have a material adverse impact on our financial position or results of operations.

Off-Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters or other matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any material liability for indemnification.

Contingencies

We have a contractual earn-out arrangement in connection with our acquisition of the HIS business, whereby Pfizer may be entitled up to an additional \$225.0 million in cash upon achievement of certain performance targets for the company for the three years ending December 31, 2019 (see Note 8: Fair Value Measurement). As of September 30, 2019, there is a remote probability that we will meet the performance targets by December 31, 2019, accordingly the estimated fair value of the contingent earn-out as of September 30, 2019 has been reduced to zero.

Commitments

We have non-cancellable operating lease agreements where we are contractually obligated to pay certain lease payment amounts (see Note 5: Leases).

Note 19: Collaborative and Other Arrangements

On February 3, 2017, we entered into two Manufacturing and Supply Agreements ("MSAs"), (i) whereby Pfizer will manufacture and supply us with certain agreed upon products for an initial five-year term with a one-time two-year option to extend and (ii) whereby we will manufacture and supply Pfizer certain agreed upon products for a term of five or ten years depending on the product, also with a one-time two-year option to extend. The MSAs provide each party with mutually beneficial interests and both of the MSAs are to be jointly managed by both Pfizer and ICU. The initial supply price, which will be annually updated, is in full consideration for all costs associated with the manufacture, documentation, packaging and certification of the products.

Note 20: Subsequent Events

On November, 8 2019, we acquired Pursuit Vascular, Inc. for approximately \$75.0 million in cash and a potential contingent earn-out of up to \$50.0 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the condensed consolidated financial statements and accompanying notes in this Form 10-Q, as well as the audited consolidated financial statements and related notes for the fiscal year ended December 31, 2018 included in our Annual Report on Form 10-K.

When used in this report, the terms "we," "us," and "our" refer to ICU Medical, Inc ("ICU") and its subsidiaries included in our condensed consolidated financial statements unless context requires otherwise.

Overview

We are one of the world's leading pure-play infusion therapy companies with global operations and a wide-ranging product portfolio that includes IV solutions, IV smart pumps with pain management and safety software technology, dedicated and non-dedicated IV sets and needlefree connectors designed to help meet clinical, safety and workflow goals. In addition, we manufacture automated pharmacy IV compounding systems with workflow technology, closed systems transfer devices for preparing and administering hazardous IV drugs, and cardiac monitoring systems for critically ill patients.

Our primary customers are acute care hospitals, wholesalers, ambulatory clinics and alternate site facilities, such as clinics, home health care providers and long-term care facilities. We sell our products in more than 90 countries throughout the world.

We categorize our products into four main product lines: Infusion Consumables, IV Solutions, Infusion Systems, and Critical Care. We have presented our financial results in accordance with these product lines, with our primary products in each line listed below.

Infusion Consumables

Infusion therapy sets, used in hospitals and ambulatory clinics, consist of a tube running from a bottle or plastic bag containing a solution to a catheter inserted in a patient's vein, that may or may not be used with an IV pump. Our primary Infusion Consumable products are:

- *Clave™ needlefree products*, including the MicroClave, MicroClave Clear, and NanoClave™ brand of connectors, accessories, extension and administration sets used for the administration of IV fluids and medications and the Neutron catheter patency device, used to help maintain patency of central venous catheters;
- *SwabCap* disinfecting cap, used to protect and disinfect any needlefree connector, including competitive brands of connectors;
- *Tego* hemodialysis connector used to cap and protect hemodialysis central venous catheter hubs; and
- *NovaCath™ and SuperCath™* peripheral IV catheters (PIV).

Closed System Transfer Devices ("CSTD") and hazardous drug compounding systems are used to prepare and deliver hazardous IV medications such as those used in chemotherapy, which, if released, can have harmful effects on the healthcare worker and environment. Our products are:

- *ChemoLock* CSTD with a proprietary and pharmacy-preferred needlefree connection method, used for the preparation and administration of hazardous drugs. ChemoLock is used to limit the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury;
- *ChemoClave*, an ISO Connection standard and universally compatible CSTD used for the preparation and administration of hazardous drugs. ChemoClave utilizes standard ISO luer locking connections, making it compatible with all brands of needlefree connectors and pump delivery systems. ChemoClave also limits the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury; and
- *Diana* hazardous drug compounding system, an automated sterile compounding system that incorporates ChemoClave and ChemoLock CSTD consumables and IV workflow technology for the accurate, safe, and efficient preparation of hazardous drugs. It is a user-controlled automated system that provides repeatable accuracy of drug mixes and minimizes clinician exposure to hazardous drugs while helping to maintain the sterility of the drugs being mixed.

The preparation of hazardous drugs typically takes place in a pharmacy location where drugs are removed from vials and prepared for delivery to a patient. Those prepared drugs are then transferred to a nursing unit where the chemotherapy is administered via an infusion pump set to a patient. Components of the ChemoClave and ChemoLock product lines are used both in pharmacies and on the nursing floors for the preparation and administration of hazardous drugs.

IV Solutions

We provide a broad portfolio of IV solutions to meet our customers' clinical needs, providing a consistent supply of IV solutions, irrigation, and nutritionals to help provide safe and effective patient care. Our primary IV Solutions products are:

IV Therapy and Diluents:

- Including Sodium Chloride, Dextrose, Balanced Electrolyte Solutions, Lactated Ringer's, Ringer's, Mannitol, Sodium Chloride/Dextrose and Sterile Water

Irrigation:

- Including Sodium Chloride Irrigation, Sterile Water Irrigation, Physiologic Solutions, Ringer's Irrigation, Ringer's Irrigation, Acetic Acid Irrigation, Glycine Irrigation, Sorbitol-Mannitol Irrigation, Flexible Containers and Pour Bottle Options

Infusion Systems

We offer a wide range of infusion pumps, dedicated IV sets and software. Our primary Infusion System products are dedicated IV sets and the following:

Infusion Pump Hardware:

- *Plum 360™*: The Plum 360™ infusion pump is an ICU Medical MedNet™ ready large volume infusion pump with an extensive drug library and wireless capability. Plum 360 was named the 2018 Best in KLAS winner as top-performing IV smart pump and is the first medical device to be awarded UL Cybersecurity Assurance Program Certification; and
- *LifeCare PCA™*: The LifeCare PCA infusion pump is an ICU Medical MedNet™ ready patient-controlled analgesia pump ("PCA"), providing complete IV-EHR interoperability since 2016.

IV Medication Safety Software:

- *ICU Medical MedNet™*: ICU Medical MedNet is an enterprise-class medication management platform for any sized healthcare system that can help reduce medication errors, improve quality of care, streamline workflows and maximize revenue capture. ICU Medical MedNet connects our industry-leading smart pumps to a hospital's Electronic Health Records ("EHR"), asset tracking systems, and alarm notification platforms with the largest array of integration partners.

Professional Services:

- In addition to the products above, our teams of clinical, information technology, and professional services experts work with customers to develop and deliver safe and efficient infusion systems, providing customized and personalized configuration, implementation, and data analytics services to complement our infusion hardware and software.

Critical Care

Our Critical Care products help clinicians get accurate real-time access to patients' hemodynamic and cardiac status with an extensive portfolio of monitoring systems and advanced sensors & catheters. Measurements provided by our systems help clinicians determine how well the heart is pumping blood and how efficiently oxygen from the blood is being used by the tissues. Our primary Critical Care products are:

- Cogent™ 2-in-1 hemodynamic monitoring system
- CardioFlo™ hemodynamic monitoring system
- TDQ™ and OptiQ™ cardiac output monitoring catheters
- Transpac™ blood pressure transducers
- SafeSet™ closed blood sampling and conservation system

The following table summarizes our total worldwide revenue by domestic and international markets by amount and as a percentage of total revenue (in millions, except percentages):

	Three months ended September 30,				Nine months ended September 30,			
	2019		2018		2019		2018	
	\$	% of Revenue	\$	% of Revenue	\$	% of Revenue	\$	% of Revenue
Domestic	\$ 222.6	72%	\$ 244.9	75%	\$ 697.5	73%	\$ 801.3	76%
International	84.9	28%	82.3	25%	253.2	27%	258.4	24%
Total Revenue	\$ 307.5	100%	\$ 327.2	100%	\$ 950.7	100%	\$ 1,059.7	100%

The following table sets forth, for the periods indicated, total revenue by product line as a percentage of total revenue:

Product line	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Infusion Consumables	39%	36%	38%	34%
IV Solutions	32%	35%	33%	37%
Infusion Systems	26%	25%	26%	25%
Critical Care	3%	4%	3%	4%
	100%	100%	100%	100%

We manage our product distribution in the U.S. through a network of three owned distribution facilities, as well as, through direct channels, which include independent distributors and the end users of our products, and as original equipment manufacturer suppliers. Most of our independent distributors handle the full line of our products. Internationally, we manage our operations through the Netherlands, which utilizes international regional hubs. We also manage our operations through independent distributors.

A substantial amount of our products are sold to Group Purchasing Organization member hospitals. We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships to secure long-term contracts with large healthcare providers and major buying organizations. Although we believe that we are not dependent on any single distributor for distribution of our products, the loss of a strategic relationship with a customer could have a material adverse effect on our operating results.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product acquisition and development; however, there is no assurance that we will be successful in implementing our growth strategy. Product development or acquisition efforts may not succeed, and even if we do develop or acquire additional products, there is no assurance that we will achieve profitable sales of such products. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

Seasonality/Quarterly Results

There are no significant seasonal aspects to our business. We may experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, rather than by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

Consolidated Results of Operations

We present income statement data in Part I, Item 1 - Financial Statements. The following table shows, for the three and nine months ended September 30, 2019 and 2018, the percentages of each income statement caption in relation to total revenue:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Total revenue	100 %	100%	100 %	100 %
Gross margin	39 %	41%	38 %	41 %
Selling, general and administrative expenses	21 %	24%	22 %	23 %
Research and development expenses	4 %	4%	4 %	4 %
Restructuring and strategic transaction	3 %	7%	7 %	6 %
Change in fair value of contingent earn-out	— %	6%	(5)%	2 %
Contract settlement	— %	—%	— %	3 %
Total operating expenses	28 %	41%	28 %	38 %
Income from operations	11 %	—%	10 %	3 %
Interest expense	— %	—%	— %	— %
Other income, net	— %	—%	— %	— %
Income before income taxes	11 %	—%	10 %	3 %
(Provision) Benefit for income taxes	(2)%	—%	(1)%	— %
Net income	9 %	—%	9 %	3 %

In addition to comparing changes in revenue on a U.S. GAAP basis, we also compare the changes in revenue from one period to another using constant currency. We provide constant currency information to enhance the visibility of underlying business trends, excluding the effects of changes in foreign currency translation rates. To calculate our constant currency results, we apply the average exchange rate for revenues from the prior year to the current year results. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as we present them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.

Infusion Consumables

The following table summarizes our total Infusion Consumables revenue (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
Infusion Consumables	\$ 119.8	\$ 117.8	\$ 2.0	1.7%	\$ 358.0	\$ 361.5	\$ (3.5)	(1.0)%

Infusion Consumables revenue increased for the three months ended September 30, 2019 and decreased for the nine months ended September 30, 2019, as compared to the same periods in the prior year. For the three months ended September 30, 2019, the Infusion Consumables revenue increased primarily due to improvements in the temporary supply constraints in our oncology products and the timing of orders, which was partially offset by the impact of exchange rates. On a constant currency basis, Infusion Consumables revenue would have been \$121.4 million for the three months ended September 30, 2019, an increase of \$3.6 million or 3.1%, as compared to the same period in the prior year.

For the nine months ended September 30, 2019, Infusion Consumables revenue was mostly impacted by exchange rates. On a constant currency basis, Infusion Consumables revenue would have been \$365.1 million for the nine months ended September 30, 2019, an increase of \$3.6 million or 1.0% as compared to the same period in the prior year.

IV Solutions

The following table summarizes our total IV Solutions revenue (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
IV Solutions	\$ 98.2	\$ 114.4	\$ (16.2)	(14.2)%	\$ 314.0	\$ 394.2	\$ (80.2)	(20.3)%

IV Solutions sales decreased for the three and nine months ended September 30, 2019, as compared to the same periods in the prior year. Supply constraints at our competitors beginning in the second quarter of 2017 and continuing through 2018 caused some temporary customer purchases and stock-up on supplies of IV Solutions in the three and nine months ended September 30, 2018. These market shortages temporarily drove up the demand for our product during those periods. In addition, most of the temporary increase in IV Solutions sales that we had as a result of competitor supply constraints has returned to its original contract supplier.

Infusion Systems

The following table summarizes our total Infusion Systems revenue (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
Infusion Systems	\$ 78.9	\$ 81.5	\$ (2.6)	(3.2)%	\$ 244.5	\$ 263.3	\$ (18.8)	(7.1)%

Infusion Systems revenue decreased for the three and nine months ended September 30, 2019, as compared to the same periods in the prior year. For the three months ended September 30, 2019, the decrease in revenue, as compared to the prior year comparable period, was primarily due to the impact of exchange rates. For the nine months ended September 30, 2019, the decrease in revenue, as compared to the prior year comparable period was primarily due to the impact of exchange rates and net historical losses in our U.S. installed base of infusion pumps. On a constant currency basis Infusion Systems revenue would have been \$81.0 million for the three months ended September 30, 2019, a decrease of \$0.5 million or 0.6%, as compared to the same period in the prior year. On a constant currency basis Infusion Systems revenue would have been \$253.5 million for the nine months ended September 30, 2019, a decrease of \$9.8 million or 3.7%, as compared to the same period in the prior year.

Critical Care

The following table summarizes our total Critical Care revenue (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
Critical Care	\$ 10.6	\$ 13.5	\$ (2.9)	(21.5)%	\$ 34.2	\$ 40.7	\$ (6.5)	(16.0)%

Critical Care revenue decreased for the three and nine months ended September 30, 2019, as compared to the same periods in the prior year, primarily due to supply constraints.

Gross Margins

For the three and nine months ended September 30, 2019, gross margins were 38.6% and 37.6%, respectively, as compared to 41.1% for both the three and nine months ended September 30, 2018. The decrease in gross margin for the three and nine months ended September 30, 2019, as compared to the same period in the prior year was primarily due to the

slowdown in manufacturing of IV Solutions and additional supply chain costs related to higher than optimal inventory levels. The nine months ended September 30, 2019, also included a one-time supply chain inventory optimization charge of \$16.3 million for the initial ramp down of IV Solution production to align supply to market demand. We have no further significant plans in regard to the ramp down of IV Solution production for the remainder of the year.

Selling, General and Administrative (“SG&A”) Expenses

The following table summarizes our total SG&A Expenses (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
SG&A	\$ 65.9	\$ 76.6	\$ (10.7)	(14.0)%	\$ 206.3	\$ 243.5	\$ (37.2)	(15.3)%

SG&A expenses decreased for the three and nine months ended September 30, 2019, as compared to the same periods in the prior year. For the three months ended September 30, 2019 as compared to the same period in the prior year, consulting expense decreased \$10.9 million, stock based compensation decreased \$2.7 million, compensation expense decreased \$1.5 million and information technology expenses decreased \$1.2 million. Partially offsetting these decreases was a \$3.0 million increase in depreciation expense, and a \$1.7 million increase in bad debt expense. Consulting expense decreased as our transitional services agreement with Pfizer ended in the fourth quarter of 2018. Stock based compensation decreased in the current period due to an adjustment for changes in the number of performance shares estimated to vest. Compensation expense decreased in the current period as incentive bonuses were higher in the prior year due to company performance. Information technology expenses decreased as software maintenance costs decreased in the current period. Depreciation expense increased due to an increase in the depreciable asset base related to the HIS integration. Bad debt expense increased as a result of our assessment of our reserves related to our accounts receivable.

For the nine months ended September 30, 2019 as compared to the same period in the prior year, consulting expenses decreased \$33.6 million, compensation expense decreased \$9.6 million, legal expense decreased \$4.0 million, information technology expenses decreased \$3.8 million, stock based compensation decreased \$2.5 million and travel expenses decreased \$2.3 million. Partially offsetting these decreases was a \$8.3 million increase in depreciation and amortization and a \$7.4 million increase in bad debt and warranty expense. Consulting expense decreased as our transitional services agreement with Pfizer ended in the fourth quarter of 2018. Compensation expense decreased in the current period as incentive bonuses were higher in the prior year due to company performance. Legal expenses were higher in the prior year due to expenses incurred related to the contract settlement, discussed below. Information technology expenses decreased as software maintenance costs decreased in the current period. Stock based compensation decreased due to an adjustment for changes in the number of performance shares estimated to vest. Depreciation expense increased due to an increase in the depreciable asset base related to the HIS integration. Bad debt expense increased as a result of the quarterly assessment of our reserves related to our accounts receivable.

We reclassified \$1.4 million and \$5.1 million of foreign exchange losses from SG&A for the three and nine months ended September 30, 2018, respectively, to other income (expense), net to conform to our current year reporting of those gains and losses, see below.

Research and Development (“R&D”) Expenses

The following table summarizes our total R&D Expenses (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2019	2018	\$ Change	% Change	2019	2018	\$ Change	% Change
R&D	\$ 12.0	\$ 13.2	\$ (1.2)	(9.1)%	\$ 36.0	\$ 39.3	\$ (3.3)	(8.4)%

R&D expenses decreased slightly for the three and nine months ended September 30, 2019, as compared to the same periods in the prior year. The current year expense is primarily related to compensation and benefit expenses incurred on our current R&D projects.

Restructuring and Strategic Transaction and Integration Expenses

Restructuring and strategic transaction and integration expenses were \$8.0 million and \$69.4 million for the three and nine months ended September 30, 2019, respectively, as compared to \$24.0 million and \$64.3 million for the three and nine months ended September 30, 2018, respectively.

Restructuring charges

Restructuring charges were \$0.8 million and \$8.4 million for the three and nine months ended September 30, 2019, respectively, as compared to \$0.5 million and \$3.0 million for the three and nine months ended September 30, 2018, respectively. Restructuring charges for the three and nine months ended September 30, 2019, were primarily related to a one-time charge to move our U.S. pump service depot to our existing Salt Lake City facility and other plant restructuring. For the three and nine months ended September 30, 2018, the restructuring charges were related to the integration of our acquired HIS business. We expect to pay unpaid restructuring charges as of September 30, 2019, by early 2020.

Strategic transaction and integration expenses

Strategic transaction and integration expenses were \$7.2 million and \$61.0 million for the three and nine months ended September 30, 2019, respectively, as compared to \$23.5 million and \$61.3 for the three and nine months ended September 30, 2018, respectively. The strategic transaction and integration expenses during the three and nine months ended September 30, 2019 were primarily related to the integration of the HIS business. During the nine months ended September 30, 2019, the strategic transaction and integration expenses also included a one-time strategic supply chain restructuring charge of \$22.1 million, which reduces our contracted commitments to our third party manufacturer and charges related to our final Pfizer separation costs and clean-up, which for the nine months ended September 30, 2019 included a \$12.7 million non-cash write-off of related assets.

Change in Fair Value of Earn-out

We conducted a revaluation of the fair value of our HIS contingent earn-out liability that resulted in a decrease of value of \$0.2 million and \$47.4 million for the three and nine months ended September 30, 2019, respectively, as compared to an increase of value of \$18.5 million and \$20.5 million for the three and nine months ended September 30, 2018, respectively.

Contract Settlement

For the nine months ended September 30, 2019, we incurred a contract settlement expense of \$3.8 million and for the nine months ended September 30, 2018, we incurred a contract settlement expense of \$28.9 million. These expenses were related to the resolution of a dispute with a product partner, pursuant to which we renegotiated the terms of our contractual arrangement with that product partner and the associated rights and remedies.

Interest Expense

Interest expense was \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2019, as compared to \$0.3 million and \$0.5 million for the three and nine months ended September 30, 2018. The interest expense for all periods is related to the amortization of financing costs incurred as of year-end December 31, 2017, in connection with a five-year Revolving Credit Facility and a related per annum commitment fee charged on the unused portion of the revolver under such Credit Facility (see Note 16: Long-Term Obligations in our accompanying condensed consolidated financial statements for additional information).

Other Income (Expense), net

Other income (expense) netted to \$0.0 million and \$4.7 million for the three and nine months ended September 30, 2019, respectively, as compared to (\$0.5) million and (\$3.5) million for the three and nine months ended September 30, 2018, respectively. For the three and nine months ended September 30, 2019, interest income was \$1.7 million and \$5.1 million, respectively. The interest income for the three months ended September 30, 2019 was mostly offset by \$1.5 million in foreign exchange losses. In 2019, we reported foreign exchange gains and losses in other income (expense), net, accordingly for comparative purposes we reclassified prior year's foreign exchange gains and losses to other income (expense), net from SG&A. For the three and nine months ended September 30, 2018, other income (expense), net was primarily related to this reclass which resulted in net foreign exchange losses of \$1.7 million and \$5.7 million, respectively, partially offset by \$1.2 million and \$3.2 million in interest income for the three and nine months ended September 30, 2018, respectively.

Income Taxes

Income taxes were accrued at an estimated effective tax rate of 19% and 14% for the three and nine months ended September 30, 2019, respectively, as compared to 85% and (4.0)% for the three and nine months ended September 30, 2018, respectively.

The effective tax rate for the three and nine months ended September 30, 2019 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes, GILTI and tax credits. It is also affected by discrete items that may occur in any given year but are not consistent from year to year. The effective tax rate during the three and nine months ended September 30, 2019 included a discrete tax benefit of \$0.3 million and \$7.7 million, respectively, related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. The effective tax rate for the three and nine months ended September 30, 2019 is also impacted by the repatriation of certain intellectual property and assets from a liquidation of one of our foreign subsidiaries to the U.S. parent. In accordance with the changes to the accounting for income tax effects of such intra-entity transfers of assets, we recorded a net tax benefit of \$3.8 million related to the liquidation. Lastly, the effective tax rate during the three and nine months ended September 30, 2019 included a discrete tax expense of \$2.2 million related to return-to-provision adjustments for the year ended December 31, 2018 primarily due to changes in estimates for our U.S. GILTI inclusion.

The effective tax rate for the three and nine months ended September 30, 2018 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes and tax credits. The effective tax rate during the three and nine months ended September 30, 2018 included a discrete tax benefit of \$1.6 million and \$12.8 million, respectively, related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. The effective tax rate for the nine months ended September 30, 2018 was also impacted by a contract settlement. The contract settlement resulted in a tax benefit of \$5.7 million, which is treated as a discrete item.

Liquidity and Capital Resources

During the first nine months of 2019, our cash, cash equivalents, short-term and long-term investments decreased by \$47.3 million from \$384.1 million at December 31, 2018 to \$336.8 million at September 30, 2019.

Cash Flows from Operating Activities

Our net cash provided by operations for the nine months ended September 30, 2019 was \$53.1 million. Net income plus adjustments for non-cash net expenses contributed \$156.9 million. Net cash used in operations as a result of changes in operating assets and liabilities was \$103.9 million. The changes in operating assets and liabilities included a \$30.9 million increase in inventories, a \$29.5 million increase in other assets, a \$32.5 million increase in accounts receivable, a \$23.2 million decrease in accrued liabilities, and a \$3.0 million decrease in accounts payable. Offsetting these amounts was a \$8.8 million decrease in prepaid expenses and other current assets and \$6.5 million in net changes in income taxes, including excess tax benefits and deferred income taxes. The increase in inventory was primarily due to an increase in our finished goods safety stock. The increase in other assets was primarily related to the purchase of spare parts. The increase in accounts receivable is mainly due to the current year reclassification of receivables from Pfizer and the timing of revenue and collections. In the current year, receivables from Pfizer are included in accounts receivable and not in a separate related-party receivable line item as in the prior year. As of December 31, 2018, Pfizer had sold all of its shares of our common stock thereby ending its related-party relationship with us. The decrease in accrued liabilities was primarily a result of the payout of accrued compensation, partially offset by an increase in certain accruals including \$22.1 million in accrued costs related to the initial ramp down of IV Solution production. The decrease in accounts payable was due to the timing of payments. The decrease in prepaid expenses and other current assets was primarily due to the collection of receivable amounts owed from Pfizer. The net changes in income taxes was a result of the timing of payments.

Our net cash provided by operations for the nine months ended September 30, 2018 was \$110.3 million. Net income plus adjustments for non-cash net expenses contributed \$147.8 million. Net cash used in operations as a result of changes in operating assets and liabilities was \$37.5 million. The changes in operating assets and liabilities included a \$39.0 million increase in accounts receivable, an \$18.5 million decrease in accrued liabilities, \$12.4 million in net changes in income taxes, including excess tax benefits and deferred income taxes, a \$2.1 million decrease in accounts payable and a \$0.5 million increase in prepaid expenses and other assets. Offsetting these amounts was a \$31.0 million decrease in related party receivables, a \$12.2 million decrease in inventories and \$8.3 million increase in other assets. The increase in accounts receivable is due to the increase in revenue. The decrease in accrued liabilities was primarily a result of the payout of accrued compensation. The net changes in income taxes was a result of the timing of payments. The decrease in accounts payable was

due to the timing of payments. The increase in prepaid expenses and other assets was primarily due to an increase in deferred costs, deferred tax charges, and other miscellaneous prepaid expenses mostly offset by a decrease in sales tax receivables, prepaid property insurance and property taxes. The decrease in related-party receivables was primarily due to the timing of amounts received from Pfizer. The decrease in inventory was primarily due to our continued inventory reduction effort. The increase in other assets was primarily due to the purchase of spare parts.

Cash Flows from Investing Activities

The following table summarizes the changes in our investing cash flows (in thousands):

	Nine months ended September 30,		Change
	2019	2018	
Investing Cash Flows:			
Purchases of property and equipment	\$ (73,253)	\$ (75,057)	\$ 1,804 ⁽¹⁾
Proceeds from sale of assets held-for-sale	—	13,000	\$ (13,000) ⁽²⁾
Proceeds from sale of assets	19	—	19
Business acquisitions, net of cash acquired	(4,600)	(1,300)	(3,300) ⁽³⁾
Intangible asset additions	(6,461)	(5,375)	(1,086)
Purchases of investment securities	(17,994)	(30,495)	12,501 ⁽⁴⁾
Proceeds from sale of investment securities	36,400	14,940	21,460 ⁽⁵⁾
Net cash used in investing activities	\$ (65,889)	\$ (84,287)	\$ 18,398

⁽¹⁾ Our purchases of property and equipment will vary from period to period based on additional investments needed to support new and existing products and expansion of our manufacturing facilities.

⁽²⁾ In 2018, we sold the land and building related to our Dominican Republic manufacturing facilities acquired as part of the 2017 HIS acquisition.

⁽³⁾ Our business acquisitions will vary from period to period based upon our current growth strategy and our ability to execute on desirable target companies.

⁽⁴⁾ Our purchases of investment securities will vary from period to period based on current cash needs, planning for known future transactions and due to changes in our investment strategy.

⁽⁵⁾ Proceeds from the sale or maturity of our investment securities will vary from period to period based on the maturity dates of the investments we currently hold.

While we can provide no assurances, we estimate that our capital expenditures in 2019 will be approximately \$95.0 million to \$105.0 million. We anticipate making additional investments in machinery and equipment in our manufacturing operations in Costa Rica, the U.S. and Mexico to support new and existing products, in infusion products that are placed with customers outside the U.S., and in IT to benefit world-wide operations.

We expect to use our cash to fund our capital purchases. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Cash Flows from Financing Activities

The following table summarizes the changes in our financing cash flows (in thousands):

	Nine months ended September 30,		Change
	2019	2018	
Financing Cash Flows:			
Proceeds from exercise of stock options	\$ 4,240	\$ 14,211	\$ (9,971) ⁽¹⁾
Tax withholding payments related to net share settlement of equity awards	(18,478)	(6,119)	(12,359) ⁽²⁾
Net cash used in financing activities	<u>\$ (14,238)</u>	<u>\$ 8,092</u>	<u>\$ (22,330)</u>

⁽¹⁾ Proceeds from the exercise of stock options will vary from period to period based on the volume of options exercised and the exercise price of the specific options exercised.

⁽²⁾ During the nine months ended September 30, 2019, our employees surrendered 79,313 shares of our common stock from vested restricted stock awards as consideration for approximately \$18.5 million in minimum statutory withholding obligations paid on their behalf. During the nine months ended September 30, 2018, our employees surrendered 25,745 shares of our common stock from vested restricted stock awards as consideration for approximately \$6.1 million in minimum statutory withholding obligations paid on their behalf.

In August 2019, our Board of Directors approved a share purchase plan to purchase up to \$100.0 million of our common stock. This plan replaced our existing plan and has no expiration date. As of September 30, 2019, all of the \$100 million available for purchase was remaining under the plan.

We have a substantial cash and investment security position generated from operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation.

Access to Capital

We believe that our existing cash and cash equivalents along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all. Our ability to generate cash flows from operations, issue debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for our products or in the solvency of our customers or suppliers, deterioration in our key financial ratios or credit ratings or other significantly unfavorable changes in conditions.

Credit Facility

We have a five-year Senior Secured Revolving Credit Facility ("Credit Facility") with various lenders for \$150.0 million, with Wells Fargo Bank, N.A. as the administrative agent (see Note 16: Long-Term Obligations). The Credit Facility has an accordion feature that would enable us to increase the borrowing capacity of the credit facility by the greater of (i) \$100.0 million and (ii) 2.00x Total Leverage. Under the terms of the Credit Facility, we will be subject to certain financial covenants pertaining to leverage and fixed charge coverage ratios. Borrowings under the Credit Facility will bear interest at LIBOR plus an applicable margin tied to the leverage ratio in effect. The unused portion of the Credit Facility will be subject to a per annum commitment fee which is also calculated using the leverage ratio in effect. The Credit Facility matures in 2022.

Financial Covenants

The Credit Facility contains certain negative financial covenants, including, Consolidated Total Leverage and Consolidated Fixed Charge Coverage Ratios.

The Consolidated Leverage Ratio is defined as the ratio of Consolidated Total Funded Indebtedness on such date, to Consolidated Adjusted EBITDA, as defined under the Credit Facility Agreement, for the most recently completed four fiscal quarters. The maximum Consolidated Leverage Ratio is not more than 3.00 to 1.00.

The Consolidated Fixed Charge Coverage Ratio is defined as the ratio of: (a) Consolidated Adjusted EBITDA less the sum of (i) capital expenditures, (ii) federal, state, local and foreign income taxes paid in cash and (iii) cash restricted payments made after the closing date, to (b) Consolidated Fixed Charges for the most recently completed four fiscal quarters, calculated on a pro forma basis. The minimum Consolidated Fixed Charge Coverage Ratio is 2.00 to 1.00.

We were in compliance with all financial covenants as of September 30, 2019.

Off-Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any material liability for indemnification.

Contractual Obligations

There have been no material changes to our contractual obligations disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 ("Annual Report"). On January 1, 2019, we adopted Accounting Standard Update ("ASU") No. 2016-02, Leases (Topic 842). The impact of the adoption of ASU No. 2016-02 on our operating lease obligations is disclosed in Note 5 to Part I, Item 1. Financial Statements.

Critical Accounting Policies

In our Annual Report, we identified the critical accounting policies which affect our more significant estimates and assumptions used in preparing our consolidated financial statements, there have been no material changes to our critical accounting policies from those previously disclosed in our Annual Report.

New Accounting Pronouncements

See Note 2 to Part I, Item 1. Financial Statements.

Forward Looking Statements

Various portions of this Quarterly Report on Form 10-Q, including this Management's Discussion and Analysis of Financial Condition and Results of Operations, and documents referenced herein, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are "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, and we may identify them by using words such as "anticipate," "believe," "expect," "estimate," "intend," "plan," "will," "continue," "could," "may," and by similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

- future growth; future operating results and various elements of operating results, including future expenditures and effects with respect to sales and marketing and product development and acquisition efforts; future sales and unit volumes of products; expected increases and decreases in sales; deferred revenue; accruals for restructuring charges, future license, royalty and revenue share income; production costs; gross margins; litigation expense; future SG&A and R&D expenses; manufacturing expenses; future costs of expanding our business; income; losses; cash flow; amortization; source of funds for capital purchases and operations; future tax rates; alternative sources of capital or financing; changes in working capital items such as receivables and inventory; selling prices; and income taxes;
- factors affecting operating results, such as shipments to specific customers; reduced dependence on current proprietary products; loss of a strategic relationship; change in demand; domestic and international sales; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; maintaining strategic relationships and securing long-term and multi-product contracts with large healthcare providers and major buying organizations; increases in

systems capabilities; introduction, development and sales of new products, acquisition and integration of businesses and product lines; benefits of our products over competing systems; qualification of our new products for the expedited Section 510(k) clearance procedure; possibility of lengthier clearance process for new products; planned increases in marketing; warranty claims; rebates; product returns; bad debt expense; amortization expense; inventory requirements; lives of property and equipment; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment or expansion of production facilities inside or outside of the United States; planned new orders for semi-automated or fully automated assembly machines for new products; adequacy of production capacity; results of R&D; our plans to repurchase shares of our common stock; asset impairment losses; relocation of manufacturing facilities and personnel; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

- new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; loss of larger distributors and the ability to locate other distributors; growth of our Clave products in future years; design features of Clave products; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; patent protection and intellectual property landscape; patent infringement claims and the impact of newly issued patents on other medical devices; competitive and market factors, including continuing development of competing products by other manufacturers; improved production processes and higher volume production; innovation requirements; consolidation of the healthcare provider market and downward pressure on selling prices; distribution or financial capabilities of competitors; healthcare reform legislation; use of treasury stock; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; foreign currency denominated financial instruments; foreign exchange risk; commodity price risk; our expectations regarding liquidity and capital resources over the next twelve months; capital expenditures; plans to convert existing space; acquisitions of other businesses or product lines, indemnification liabilities and contractual liabilities.

Forward-looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, investors should read the forward looking statements in conjunction with the Risk Factors discussed in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2018, Part II, Item 1A of this Quarterly Report on Form 10-Q and our other reports filed with the SEC. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with Pfizer or our other large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and

- the availability of patent protection and the cost of enforcing and of defending patent claims.

The forward-looking statements in this report are subject to additional risks and uncertainties, including those detailed from time to time in our other filings with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof and, except as required by law, we undertake no obligation to update or revise any of them, whether as a result of new information, future events or otherwise.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest rate risk

If we were to incur borrowings under our Credit Facility, we would face market risk stemming from changes in interest rates.

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, accounts receivable and accounts payable and accrued liabilities.

In our European operations, our net Euro asset position at September 30, 2019 was approximately €48.3 million. A 10% change in the conversion of the Euro to the U.S. dollar for our cash, accounts receivable, accounts payable and accrued liabilities from the September 30, 2019 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$5.3 million, or 0.7% of these consolidated net assets. We expect that in the future, with the growth of our European distribution operations, net Euro denominated instruments will continue to increase. In our Canadian operations, our net Canadian dollar asset position at September 30, 2019 was approximately \$37.5 million. A 10% change in the conversion of the Canadian dollar to the U.S. dollar for our cash, accounts receivable, accounts payable and accrued liabilities from the September 30, 2019 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$2.6 million, or 0.3% of these net assets. We currently do not hedge our Canadian dollar or Euro foreign currency exposures.

We have manufacturing facilities and conduct business transactions denominated in the Mexican Peso. We hedge a portion of our manufacturing spend, which reduces our exposure to the foreign currency exchange risk related to the Mexican Peso (see Note 7: Derivatives and Hedging to the condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q).

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

There was no change in our internal control over financial reporting during the quarter ended September 30, 2019 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Certain legal proceedings in which we are involved are discussed in Part I, Item 1. "Financial Statements" of this Form 10-Q in Note 18. Commitments and Contingencies to the Condensed Consolidated Financial Statements, and is incorporated herein by reference.

Item 1A. Risk Factors

In evaluating an investment in our common stock, investors should consider carefully, among other things, the risk factors previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2018, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds*Purchase of Equity Securities*

The following is a summary of our stock repurchasing activity during the third quarter of 2019:

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program ⁽¹⁾
07/01/2019 — 07/31/2019	—	\$ —	—	\$ 100,000,000
08/01/2019 — 08/31/2019	—	\$ —	—	\$ 100,000,000
09/01/2019 — 09/30/2019	—	\$ —	—	\$ 100,000,000
Third quarter of 2019 total	—	\$ —	—	\$ 100,000,000

⁽¹⁾ Our common stock purchase plan, which authorized the repurchase of up to \$100.0 million of our common stock, was authorized by our Board of Directors and publicly announced in August, 2019. This plan has no expiration date. We are not obligated to make any purchases under our stock purchase program. Subject to applicable state and federal corporate and securities laws, purchases under a stock purchase program may be made at such times and in such amounts as we deem appropriate. Purchases made under our stock purchase program can be discontinued at any time we feel additional purchases are not warranted.

Item 6. Exhibits

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

Signature

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.

ICU Medical, Inc.

(Registrant)

/s/ Scott E. Lamb

Date: November 12, 2019

Scott E. Lamb

Chief Financial Officer

(Principal Financial Officer)

Exhibit Index

Exhibit 31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Exhibit 101.INS	XBRL Instance Document - this instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vivek Jain, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Vivek Jain

Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott E. Lamb, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Scott E. Lamb

Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vivek Jain, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2019

/s/ Vivek Jain

Vivek Jain

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott E. Lamb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 12, 2019

/s/ Scott E. Lamb

Scott E. Lamb
