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

FORM 10-Q

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

For the quarterly period ended: September 30, 2016
Or

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

For the transition period from: to

Commission File No.: 001-34634

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0022692**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
951 Calle Amanecer, San Clemente, California	**92673**
(Address of principal executive offices)	(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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, 2016**
Common	16,330,311

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

ICU MEDICAL, INC. AND SUBSIDIARIES
Form 10-Q
September 30, 2016

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PART I - FINANCIAL INFORMATION
Item1. Financial Statements (Unaudited)

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

	September 30, 2016	December 31, 2015
	(Unaudited)	(1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 322,963	$ 336,164
Short-term investment securities	49,475	41,233
TOTAL CASH, CASH EQUIVALENTS AND INVESTMENT SECURITIES	372,438	377,397
Accounts receivable, net of allowance for doubtful accounts of $1,121 at September 30, 2016 and $1,101 at December 31, 2015	53,638	57,847
Inventories	50,953	43,632
Prepaid income taxes	15,202	14,366
Prepaid expenses and other current assets	6,569	7,631
Assets held-for-sale	4,249	4,134
TOTAL CURRENT ASSETS	503,049	505,007
PROPERTY AND EQUIPMENT, net	80,588	74,320
LONG-TERM INVESTMENT SECURITIES	57,162	—
GOODWILL	5,577	6,463
INTANGIBLE ASSETS, net	22,832	23,936
DEFERRED INCOME TAXES	19,491	17,099
TOTAL ASSETS	$ 688,699	$ 626,825
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 12,555	$ 13,670
Accrued liabilities	19,961	28,948
TOTAL CURRENT LIABILITIES	32,516	42,618
LONG-TERM LIABILITIES	1,197	1,476
DEFERRED INCOME TAXES	5,022	1,372
INCOME TAX LIABILITY	1,488	1,488
COMMITMENTS AND CONTINGENCIES	—	—
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, 16,307 shares at September 30, 2016 and 16,086 shares at December 31, 2015	1,631	1,608
Additional paid-in capital	157,603	145,125
Retained earnings	507,468	453,896
Accumulated other comprehensive loss	(18,226)	(20,758)
TOTAL STOCKHOLDERS' EQUITY	648,476	579,871
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 688,699	$ 626,825

(1) December 31, 2015 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 INCOME (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
REVENUE:				
Net sales	$ 97,098	$ 85,891	$ 283,659	$ 250,876
Other	10	125	25	405
TOTAL REVENUE	97,108	86,016	283,684	251,281
COST OF GOODS SOLD	45,835	39,751	133,046	118,741
GROSS PROFIT	51,273	46,265	150,638	132,540
OPERATING EXPENSES:				
Selling, general and administrative	22,362	20,206	66,828	60,698
Research and development	3,650	4,227	10,301	11,657
Restructuring and strategic transaction	2,806	3,411	4,339	3,411
Gain on sale of building	—	(1,086)	—	(1,086)
Legal settlement	—	(5,261)	—	1,798
TOTAL OPERATING EXPENSES	28,818	21,497	81,468	76,478
INCOME FROM OPERATIONS	22,455	24,768	69,170	56,062
BARGAIN PURCHASE GAIN	346	—	1,456	—
OTHER INCOME, net	225	230	449	996
INCOME BEFORE INCOME TAXES	23,026	24,998	71,075	57,058
PROVISION FOR INCOME TAXES	(4,220)	(8,732)	(17,503)	(17,536)
NET INCOME	$ 18,806	$ 16,266	$ 53,572	$ 39,522
NET INCOME PER SHARE				
Basic	$ 1.16	$ 1.02	$ 3.32	$ 2.50
Diluted	$ 1.09	$ 0.98	$ 3.13	$ 2.41
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	16,200	15,894	16,113	15,790
Diluted	17,286	16,575	17,100	16,409

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
NET INCOME	$ 18,806	$ 16,266	$ 53,572	$ 39,522
Other comprehensive income (loss), net of tax of $(19) and $345 for the three months ended September 30, 2016 and 2015, respectively and $394 and $(1,867) for the nine months ended September 30, 2016 and 2015, respectively.				
Foreign currency translation adjustment	700	504	2,532	(7,719)
TOTAL COMPREHENSIVE INCOME	$ 19,506	$ 16,770	$ 56,104	$ 31,803

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

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

	Nine months ended September 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 53,572	$ 39,522
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,351	13,266
Provision for doubtful accounts	—	53
Provision for warranty and returns	(22)	38
Stock compensation	11,464	9,305
Loss (gain) on disposal of property and equipment	40	(1,102)
Bond premium amortization	1,026	1,451
Bargain purchase gain	(1,456)	—
Other	69	—
Cash provided by (used in) changes in operating assets and liabilities		
Accounts receivable	4,736	(11,390)
Inventories	(6,635)	(4,867)
Prepaid expenses and other assets	(2,228)	(8,824)
Accounts payable	(1,587)	3,246
Accrued liabilities	(7,314)	6,915
Income taxes, including excess tax benefits and deferred income taxes	2,691	1,017
Net cash provided by operating activities	68,707	48,630
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(15,018)	(7,729)
Proceeds from sale of asset	1	3,592
Business acquisitions, net of cash acquired	(2,584)	—
Intangible asset additions	(861)	(778)
Purchases of investment securities	(111,575)	(40,217)
Proceeds from sale of investment securities	45,429	70,293
Net cash (used in) provided by investing activities	(84,608)	25,161
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	15,830	10,974
Proceeds from employee stock purchase plan	2,361	2,162
Purchase of treasury stock	(17,155)	(1,523)
Net cash provided by financing activities	1,036	11,613
Effect of exchange rate changes on cash	1,664	(5,848)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(13,201)	79,556
CASH AND CASH EQUIVALENTS, beginning of period	336,164	275,812
CASH AND CASH EQUIVALENTS, end of period	$ 322,963	$ 355,368
NON-CASH INVESTING ACTIVITIES		
Accounts payable for property and equipment	$ 595	$ 1,106

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

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

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., a Delaware corporation, filed with the SEC for the year ended December 31, 2015.

We operate in one business segment engaged in the development, manufacturing and sale of innovative medical devices used in infusion therapy, critical care and oncology 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.

Note 2: New Accounting Pronouncements

Recently Adopted Accounting Standards

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments address several aspects of the accounting for share-based payment award transactions, including income tax accounting consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this update are effective for annual periods beginning after December 15, 2016. Early adoption is permitted for an entity in any interim or annual period. An entity that elects early adoption must adopt all of the amendments in the same period and any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. We early adopted this standard during the second quarter ended June 30, 2016. As of the three and nine months ended September 30, 2016, respectively, in accordance with the changes required by this ASU, we have recognized $3.6 million and $6.6 million in tax benefits as a discrete item during those periods. As we elected to retrospectively adopt the presentation of excess tax benefits as an operating activity inflow rather than as a financing activity inflow on the statement of cash flows our operating cash flows includes a $6.6 million and $6.2 million increase in operating cash flows for the periods ended September 30, 2016 and 2015, respectively, and a corresponding $6.6 million and $6.2 million decrease in financing cash flows for the same respective periods. We elect to account for forfeitures as they occur.

In September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. ASU 2015-16 requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined, including the cumulative effect of the change in provisional amount as if the accounting had been completed at the acquisition date. The adjustments related to previous reporting periods since the acquisition date must be disclosed by income statement line item either on the face of the income statement or in the notes. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2015. The adoption of this ASU did not have a material impact on our consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period. ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Entities

may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We adopted this ASU on a prospective basis. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued Accounting Standards

In October 2016, the FASB issued No. ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory. Current generally accepted accounting principles prohibits the recognition of current and deferred income taxes for an intra-entity asset transfer until after the asset has been sold to an outside party. The amendments in ASU 2016-16 eliminates this prohibition, accordingly an entity should recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. Amendments in this update are effective for annual reporting periods beginning after December 15, 2017. Early adoption is permitted in the first interim period of an annual reporting period. The amendments should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In August 2016, the FASB issued No. ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 provides specific guidance on eight cash flow issues where current guidance is unclear or does not include any specifics on classification. The eight specific cash flow issues are: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with zero coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies, including bank-owned policies; distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The amendments in ASU 2016-15 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2017. Early adoption is permitted. If adopted in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. Amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued No. ASU 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. The amendments in this update 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.

In February 2016, the FASB issued No. ASU 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 amendments in this update will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. 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.

In January 2016, the FASB issued No. ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amends certain aspects of recognition, measurement, presentation and disclosure of financial instruments. This amendment requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in the consolidation of the investee). The amendments in this update will be effective for fiscal years beginning after December 15, 2017. Early adoption of the amendments is not permitted with the exception of the provision requiring the recognition in other comprehensive income the fair value change from instrument-specific credit risk measured using the fair value option for financial instruments. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In July 2015, the FASB issued No. ASU No. 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 changes the measurement of inventory from lower of cost or market to lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2016. We do not anticipate a material impact on our consolidated financial statements from the adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. This guidance requires that an entity depict the consideration by applying a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU 2014-09. On July 15, 2015, the FASB affirmed these changes, which requires public entities to apply the amendments in ASU 2014-09 for annual reporting beginning after December 15, 2017. Early adoption is permitted beginning after December 31, 2016, the original effective date in ASU 2014-09. Subsequent to the issuance of this ASU, the FASB issued three amendments: ASU No. 2016-08 which clarifies principal versus agent considerations; ASU 2016-10 which clarifies guidance related to identifying performance obligations and licensing implementation; and ASU 2016-12 which provides narrow-scope improvements and practical expedients. All of the amendments have the same effective dates mentioned above. We do not anticipate a material impact on our consolidated financial statements from adoption of any of the above ASUs. We expect to adopt the full retrospective transition method when adopting this ASU.

Note 3: Restructuring Charges

Restructuring Charges

During the year ended December 31, 2015, we incurred restructuring charges related to: (i) 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; (ii) the reorganization of our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs; and (iii) a commitment to a plan to sell our Slovakia manufacturing facility. The assets of the manufacturing facility are classified as assets held for sale and are included as a separate line item in our condensed consolidated balance sheet. The sale is expected to be completed during the last quarter of 2016. The plan to close the facility resulted in a pre-tax restructuring charge for employee termination benefits, government incentive repayments and other associated costs. There was $0.4 million and $0.8 million in restructuring charges incurred for the three and nine months ended September 30, 2016, respectively. Of these charges, for the nine months ended September 30, 2016 $0.6 million were related to the closure of the Slovakian manufacturing facility and are included in the below table, and the other $0.2 million was related to a one-time charge unrelated to the events disclosed above.

The following table summarizes the details of changes in our restructuring-related accrual for the period ending September 30, 2016 (in thousands):

	Accrued Balance December 31, 2015	Charges Incurred	Payments	Currency Translation	Other Adjustments	Accrued Balance September 30, 2016
Severance pay and benefits	$ 2,505	$ 25	$ (2,479)	$ 89	$ 150	$ 290
Government incentive repayment	1,884	—	(1,769)	57	(172)	—
Employment agreement buyout	1,845	—	(278)	—	—	1,567
Other corporate restructuring	305	168	(386)	—	—	87
Retention and closure expenses	—	428	(428)	—	—	—
	$ 6,539	$ 621	$ (5,340)	$ 146	$ (22)	$ 1,944

Note 4: Acquisition and Strategic Transaction Expenses

Pending Acquisition

On October 6, 2016, we entered into a Stock and Asset Purchase Agreement (the “Purchase Agreement”) to acquire Pfizer Inc.’s (“Pfizer”) Hospira Infusion Systems (“HIS”) business for total consideration of approximately $601.0 million in cash and 3.2 million shares of our common stock, to be issued to Pfizer at the closing of the transaction. We believe that the acquisition of the HIS business complements our existing business by creating a company that has a complete intravenous therapy product portfolio. We also believe that the acquisition also significantly enhances our global footprint and platform for continued competitiveness and growth. Closing of the transaction is subject to certain conditions, including certain regulatory approvals. We expect the acquisition will close in the first quarter of the 2017 calendar year.

Acquisition

On April 4, 2016, we acquired all of the outstanding shares of Tangent Medical Technologies, Inc. ("Tangent") for $2.6 million in cash. Tangent designs, develops, and commercializes intravenous catheters and associated products for the improvement of infusion therapy. Tangent's products enhance our infusion therapy product offering. For the three and nine months ended September 30, 2016, we recognized a $0.3 million and $1.5 million bargain purchase gain related to the acquisition, respectively, that represented the excess of the estimated fair market value of the identifiable tangible and intangible assets acquired, liabilities assumed and deferred tax assets over the total purchase consideration. The bargain purchase was driven by our ability to realize acquired deferred tax assets. We recorded an immediate $1.1 million bargain gain at the time of the acquisition and subsequently adjusted the purchase price allocation and bargain gain during the third quarter of 2016 for additional deferred tax assets. The purchase price allocation is subject to further adjustment in order to account for final tax related matters.

Strategic Transaction Expenses

We incurred $2.4 million and $3.5 million in transaction costs during the three and nine months ended September 30, 2016, respectively. The transaction costs were related to our pending acquisition of HIS and our acquisition of Tangent, both mentioned above, as well as expenses related to our acquisition of EXC Holding Corp ("EXC").

Note 5: Gain on Sale of Building

On September 30, 2015, we sold an office building in our San Clemente location to George A. Lopez, M.D., a member of our Board of Directors. The building was sold for $3.6 million, its fair market value as determined by a third party. The net book value of the land and building was $2.5 million, resulting in a gain on the sale of the land and building of $1.1 million.

Note 6: Legal Settlements

For the three months ended September 30, 2015 we recorded a settlement award, net of legal fees and costs, of $5.3 million and for the nine months ended September 30, 2015 we recorded a net settlement charge of $1.8 million.

On September 23, 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us a gross settlement of $8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement.

On April 2, 2015, an arbitrator ruled on a breach of contract claim between us and a customer, Hospira, Inc., awarding Hospira $8.2 million Canadian dollars ($6.5 million U.S. dollars). The arbitrator also ruled that we pay 75% of Hospira's legal fees and expenses, which were $0.7 million U.S. dollars. As of September 30, 2015, we recorded an estimated total charge of $7.1 million related to the settlement and associated fees, which is presented as a separate line item in our condensed consolidated income statement. These charges were fully paid during the second quarter of 2015.

Note 7: Fair Value Measurement

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper and federal tax-exempt state and municipal government debt. All investment securities are considered available-for-sale and are “investment grade”, carried at fair value and there have been no gains or losses on their disposal. As of September 30, 2016, we had $30.9 million of our investment securities as Level 1 assets, which are certificates of deposit and U.S. Treasury securities with quoted prices in active markets. As of September 30, 2016, we had $75.8 million of our investment securities as

Level 2 assets, which are pre-refunded municipal securities, corporate bonds and commercial paper and are valued using observable market based inputs such as quoted prices, interest rates and yield curves.

There were no transfers between Levels during the nine months ended September 30, 2016.

The following tables provide the assets and liabilities carried at fair value measured on a recurring basis for the periods indicated (in thousands):

	Fair value measurements at September 30, 2016 using			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Short-term available for sale securities	$ 49,475	$ 13,645	$ 35,830	$ —
Long-term available for sale securities	57,162	17,206	39,956	—
Total available for sale securities	$ 106,637	$ 30,851	$ 75,786	$ —

	Fair value measurements at December 31, 2015 using			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Short-term available for sale securities	$ 41,233	$ 8,785	$ 32,448	$ —
	$ 41,233	$ 8,785	$ 32,448	$ —

In November 2015, our Board of Directors authorized the closure of our Vrable, Slovakia manufacturing facility. As a result of the closure, we reclassified the land and building related to the Slovakia facility as held for sale. Our assets held for sale are included as a separate line item in our condensed consolidated balance sheets. The initial fair value of our assets held for sale was estimated using the income approach and is based on critical estimates, judgments and assumptions derived from: analysis of market conditions; building condition; comparable properties; and rental income and expense (Level 3). Subsequent to the initial valuation, we evaluate the carrying value of our assets held for sale when circumstances indicate the carrying value of those assets may or may not be recoverable; there were no such indicators during the period ended September 30, 2016. The increase in our assets held for sale as of September 30, 2016, as compared to December 31, 2015, was due to foreign currency translation.

The following tables provide the assets and liabilities carried at fair value on a non-recurring basis for the periods indicated (in thousands):

	Fair value measurements at September 30, 2016 using			
	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 held for sale	$ 4,249	$ —	$ —	$ 4,249
	$ 4,249	$ —	$ —	$ 4,249

	Fair value measurements at December 31, 2015 using			
	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 held for sale	$ 4,134	$ —	$ —	$ 4,134
	$ 4,134	$ —	$ —	$ 4,134

Note 8: Investment Securities

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper and federal tax-exempt state and municipal government debt. All investment securities are considered available-for-sale and are "investment grade", carried at fair value, and there have been no gains or losses on their disposal. Unrealized gains and losses on available-for-sale securities, net of tax, are included in accumulated other comprehensive loss in the stockholders' equity section of our condensed consolidated balance sheets. We had no gross unrealized gains or losses on available-for-sale securities at September 30, 2016 or December 31, 2015. The scheduled maturities of the debt securities are between 2016 and 2042. All short-term investment securities are all callable within one year.

The investment securities consist of the following at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Federal and municipal tax-exempt debt securities	$ 8,794	$ 4,951
Corporate bonds	66,293	25,400
U.S. Treasury securities	30,052	7,537
Commercial paper	699	2,097
Certificates of deposit	799	1,248
Total investment securities	$ 106,637	$ 41,233

During the quarter ended September 30, 2016, we amended our investment policy to allow for the purchase of securities whose final maturities are in excess of one year. The amended policy continues to adhere to a low risk tolerance in regard to capital preservation while allowing for the achievement of higher available yields. The following table summarizes our investment securities by balance sheet classification at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Reported as:		
Short-term investment securities	$ 49,475	$ 41,233
Long-term investment securities	57,162	—
Total	$ 106,637	$ 41,233

Note 9: Inventories

Inventories consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw material	$ 28,940	$ 24,681
Work in process	4,834	4,282
Finished goods	17,179	14,669
Total inventories	$ 50,953	$ 43,632

Note 10: Property and Equipment

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

	September 30, 2016	December 31, 2015
Machinery and equipment	$ 94,446	$ 96,909
Land, building and building improvements	60,457	56,716
Molds	38,620	36,436
Computer equipment and software	26,146	23,346
Furniture and fixtures	3,499	3,638
Construction in progress	13,688	6,003
Total property and equipment, cost	236,856	223,048
Accumulated depreciation	(156,268)	(148,728)
Property and equipment, net	$ 80,588	$ 74,320

Note 11: Net Income Per Share

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options and restricted stock units(excluding stock options with an exercise price in excess of the average market value for the period), 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 because their exercise price exceeded the average market price of the common stock for the period approximated 44,000 for the nine months ended September 30, 2015. There were no anti-dilutive options for the three months ended September 30, 2016 and 2015 and no anti-dilutive options for the nine months ended September 30, 2016.

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,	
	2016	2015	2016	2015
Net income	$ 18,806	$ 16,266	$ 53,572	$ 39,522
Weighted average number of common shares outstanding (for basic calculation)	16,200	15,894	16,113	15,790
Dilutive securities[1]	1,086	681	987	619
Weighted average common and common equivalent shares outstanding (for diluted calculation)	17,286	16,575	17,100	16,409
EPS — basic	$ 1.16	$ 1.02	$ 3.32	$ 2.50
EPS — diluted	$ 1.09	$ 0.98	$ 3.13	$ 2.41

[1] During the second quarter of 2016, we early adopted ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (see Note 2: New Accounting Pronouncements). Under this ASU, the assumed proceeds from applying the treasury stock method when computing earnings per share no longer includes the amount of excess tax benefits or deficiencies that used to be recognized as additional paid-in capital. This change in the treasury stock method was made on a prospective basis, with adjustments reflected as of the beginning of the 2016 fiscal year. The changes to the treasury stock method required by this ASU impacted weighted average common and common equivalent shares outstanding by 413,000 shares and 375,000 shares for the three and nine months ended September 30, 2016, respectively.

Note 12: Major Customer

We had revenue equal to 10% or more of total revenue from one customer, Hospira, Inc., a subsidiary of Pfizer. Such revenues were 26% and 36% of total revenue for the three months ended September 30, 2016 and 2015, respectively, and 31% and 36% of total revenue for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016 and December 31, 2015, we had accounts receivable from Pfizer of 22% and 40% of consolidated accounts receivable, respectively.

Note 13: Income Taxes

Income taxes were accrued at an estimated effective tax rate of 25% and 31% for the nine months ended September 30, 2016 and 2015, respectively. Those rates differ from that computed at the federal statutory rate of 35%.

The effective tax rate for the nine months ended September 30, 2016 differs from the federal statutory rate of 35% principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities, and included material discrete tax benefits related to the adoption of ASU 2016-09.

The effective tax rate during the nine months ended September 30, 2016 included a material tax benefit of $6.6 million related to the early adoption of ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which amends current accounting to now recognize all excess tax benefits and all tax deficiencies as income tax benefit or expense in the reporting period in which they occur. The income tax benefit was treated as a discrete item when determining the annual estimated effective tax rate (see Note 2: New Accounting Pronouncements for further detail).

The effective tax rate for the nine months ended September 30, 2015 differs from the federal statutory rate principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities and material discrete tax benefits related to the impact of changes in estimates of tax reserves related to uncertainties in income taxes as a result of the favorable conclusion of recent federal and state examinations.

Note 14: Treasury Stock

In July 2010, our Board of Directors approved a common stock purchase plan to purchase up to $40.0 million of our common stock. This plan has no expiration date. For the nine months ended September 30, 2016 we purchased 174,885 shares of our common stock for $15.4 million, including commissions. As of September 30, 2016, the remaining authorized amount under this purchase plan is approximately $7.2 million. As of September 30, 2016, all of the treasury stock has been used to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

Additionally, for the nine months ended September 30, 2016, we withheld 19,717 shares of our common stock from employee vested restricted stock units in consideration for $1.8 million in payments made on the employee's behalf for their minimum statutory income tax withholding obligations.

Note 15: Commitments and Contingencies

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.

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.

Note 16: Subsequent Events

On October 6, 2016, we entered into the Purchase Agreement to acquire Pfizer's HIS business for total consideration of approximately $601.0 million in cash and 3.2 million shares of our common stock, to be issued to Pfizer at the closing of the transaction (see Note 4: Acquisition and Strategic Transaction Expenses). The cash portion of the consideration will be paid at closing using cash on hand and the issuance of new indebtedness. As such, in connection with entering into the Purchase Agreement, we entered into a debt commitment letter dated October 6, 2016, with Wells Fargo Bank, National Association, Wells Fargo Securities, LLC and Barclays Bank PLC (the "Committed Parties"), pursuant to which, the Committed Parties committed to provide us with senior secured credit facilities of up to $400 million consisting of a five-year term loan facility of $300 million and a revolving credit facility of $100 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, 2015 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.

Business Overview

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, critical care and oncology applications. Our product line includes needlefree connection devices, custom infusion sets, closed system transfer devices ("CSTD") for the handling of hazardous drugs, advanced sensor catheters, closed blood sampling systems and innovative hemodynamic monitoring systems.

Our products are used in acute care hospitals and ambulatory clinics in more than 60 countries throughout the world. 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,				Fiscal year ended			
	2016		2015		2016		2015		2015		2014	
	$	% of Revenue	$	% of Revenue	$	% of Revenue	$	% of Revenue	$	% of Revenue	$	% of Revenue
Domestic	$ 66.8	69%	$ 60.4	70%	$ 198.1	70%	$ 175.8	70%	$ 241.8	71%	$ 212.6	69%
International	30.3	31%	25.6	30%	85.6	30%	75.5	30%	99.9	29%	96.7	31%
Total Revenue	$ 97.1	100%	$ 86.0	100%	$ 283.7	100%	$ 251.3	100%	$ 341.7	100%	$ 309.3	100%

We categorize our products into three main market segments: Infusion Therapy, Critical Care and Oncology. Our primary products include:

Infusion Therapy

- Needlefree connector products
  - MicroClave® and MicroClave Clear
  - Neutron®
  - NanoClave®
  - Clave®
  - SwabCap®
- Custom infusion sets
- Tego® needlefree hemodialysis connector

Critical Care

- Hemodynamic monitoring systems
- Closed Blood Sampling and Conservation Systems
- Other Critical Care Products and Accessories

Oncology

- ChemoLock® CSTD and components
- ChemoClave® CSTD and components
- Diana™ hazardous drug compounding system

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

	Three months ended September 30,		Nine months ended September 30,		Fiscal year ended	
Product line	**2016**	**2015**	**2016**	**2015**	**2015**	**2014**
Infusion therapy	70%	72%	72%	71%	72%	70%
Critical care	14%	15%	14%	17%	16%	18%
Oncology	16%	13%	14%	12%	12%	12%
	100%	100%	100%	100%	100%	100%

We currently sell our products through direct channels, which include distributors and the end users of our products and as an original equipment manufacturer ("OEM") supplier. Most of our independent distributors handle the full line of our products.

Our largest customer has been Hospira, Inc., a subsidiary of Pfizer, Inc. ("Pfizer"), to which we distribute our products as an OEM supplier. Pfizer accounted for 31%, 36% and 36% of our worldwide revenue for the nine months ended September 30, 2016 and each of the years ended 2015 and 2014, respectively. We began this relationship in 1995 with Hospira, which was acquired by Pfizer in September 2015. Our related agreements extend through December 2018. Our agreements with Pfizer currently provide them with conditional rights to distribute certain of our Clave family and other products to certain categories of customers both in the United States ("U.S.") and foreign countries. Depending on the product and category of customer, these rights may be exclusive or nonexclusive. Pfizer purchases Clave products both as finished goods end-products for distribution to healthcare providers and in bulk for assembly into Pfizer infusion disposable products. The MicroClave, MicroClave Clear, ChemoClave CSTD and pre-pierced connector products are purchased and packaged separately as finished good end products. We also serve as the exclusive manufacturer for certain custom intravenous products that are sold by the same subsidiary. These products are promoted under the name SetSource. Our relationship with Pfizer has been important for our growth. On October 6, 2016, we announced our pending acquisition of Pfizer's HIS business. See "-Acquisitions" below for additional detail regarding the pending acquisition. By combining the HIS business with our current infusion therapy business, we believe that we will create a pure-play infusion business that will significantly enhance our global footprint, eliminate our single customer concentration risk and we believe significantly enhance our continued competitiveness and growth. We expect the acquisition will close in the first quarter of the 2017 calendar year.

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. As a result of this marketing and distribution strategy we derive most of our revenue from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for manufacturing customers' products 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

The healthcare business in the U.S. is subject to quarterly fluctuations due to frequency of illness during the seasons, elective procedures, and over the last few years, the economy. In Europe, the healthcare business generally slows down in the summer months due to vacations resulting in fewer elective surgeries. In addition, we can 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, and less 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.

Acquisitions

On October 6, 2016, we entered into a Purchase Agreement to acquire Pfizer's HIS business for total consideration of approximately $601.0 million in cash and 3.2 million shares of our common stock, to be issued to Pfizer at the closing of the transaction. We believe that the acquisition of the HIS business complements our existing business by creating a company that has a complete intravenous therapy product portfolio. Closing of the transaction is subject to certain conditions, including certain regulatory approvals. We expect the acquisition will close in the first quarter of the 2017 calendar year.

On April 4, 2016, we acquired all of the outstanding shares of Tangent Medical Technologies, Inc. ("Tangent") for $2.6 million in cash. Tangent designs, develops, and commercializes intravenous catheters and associated products for the improvement of infusion therapy. We believe that Tangent's products enhance our infusion therapy product offering. We do not expect any significant commercial results from this product line over the next eighteen to twenty-four months while we make changes to this product.

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, 2016 and 2015, respectively, and the year ended December 31, 2015, the percentages of each income statement caption in relation to total revenue:

	Three months ended September 30,		Nine Months Ended September 30,		Fiscal year ended
	2016	2015	2016	2015	2015
Total revenue	100%	100%	100%	100%	100%
Gross margin	53%	54%	53%	53%	53%
Selling, general and administrative expenses	23%	23%	24%	24%	24%
Research and development expenses	4%	5%	3%	5%	5%
Restructuring and strategic transaction	3%	4%	2%	1%	2%
Gain on sale of building	—%	1%	—%	1%	—%
Legal settlements	—%	6%	—%	1%	1%
Impairment of assets held for sale	—%	—%	—%	—%	1%
Total operating expenses	30%	25%	29%	30%	33%
Income from operations	23%	29%	24%	23%	20%
Bargain purchase gain	—%	—%	1%	—%	—%
Other income, net	—%	—%	—%	—%	—%
Income before income taxes	23%	29%	25%	23%	20%
Income taxes	4%	10%	6%	7%	7%
Net income	19%	19%	19%	16%	13%

Infusion Therapy Revenue

The following table summarizes our total infusion therapy revenue by direct and OEM distribution channels (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2016	2015	$ Change	% Change	2016	2015	$ Change	% Change
Direct	$ 45.0	$ 33.3	$ 11.7	35.1 %	$ 119.1	$ 95.9	$ 23.2	24.2%
OEM	22.6	29.0	(6.4)	(22.1)%	84.1	83.3	0.8	1.0%
Total Infusion Therapy Revenue	$ 67.6	$ 62.3	$ 5.3	8.5 %	$ 203.2	$ 179.2	$ 24.0	13.4%

Direct infusion therapy sales increased for the three and nine months ended September 30, 2016, as compared to the same period in the prior year, primarily due to sales of our SwabCap product-line, which was acquired through an acquisition in October 2015, and our Clave product-lines as a result of new customer sales and an increase in sales to existing customers.

OEM infusion therapy sales decreased for the three months ended September 30, 2016, as compared to the same period in the prior year, primarily due to a decrease in sales of our Clave product lines to our major OEM customer. OEM infusion therapy sales increased for the nine months ended September 30, 2016, as compared to the same period in the prior year, primarily as a result of the sales of our OEM SwabCap product, which were mostly offset by a decrease in sales of our Clave product lines.

Critical Care Revenue

The following table summarizes our total critical care revenue by direct and OEM distribution channels (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2016	2015	$ Change	% Change	2016	2015	$ Change	% Change
Direct	$ 14.0	$ 12.5	$ 1.5	12.0%	$ 40.2	$ 41.0	$ (0.8)	(2.0)%
OEM	—	—	—	—%	0.1	0.2	(0.1)	(50.0)%
Total Critical Care Revenue	$ 14.0	$ 12.5	$ 1.5	12.0%	$ 40.3	$ 41.2	$ (0.9)	(2.2)%

Direct critical care sales increased for the three months ended September 30, 2016, as compared to the same period in the prior year, primarily due to increased international sales of our hemodynamic monitoring system. Direct critical care sales decreased for the nine months ended September 30, 2016, as compared to the same period in the prior year, primarily due to an overall decline of both international and U.S. sales as a result of temporary production constraints in the first part of the year.

Oncology Revenue

The following table summarizes our total oncology revenue by direct and OEM distribution channels (in millions):

	Three months ended September 30,				Nine months ended September 30,			
	2016	2015	$ Change	% Change	2016	2015	$ Change	% Change
Direct	$ 10.8	$ 7.6	$ 3.2	42.1%	$ 28.1	$ 19.6	$ 8.5	43.4%
OEM	4.4	3.4	1.0	29.4%	11.4	10.3	1.1	10.7%
Total Oncology Revenue	$ 15.2	$ 11.0	$ 4.2	38.2%	$ 39.5	$ 29.9	$ 9.6	32.1%

Direct oncology sales increased for the three and nine months ended September 30, 2016, as compared to the same period in the prior year, primarily due to increased U.S. sales. These increases were a result of new customer sales and an increase in sales to existing customers of our ChemoClave and ChemoLock products.

OEM oncology sales increased during the three and nine months ended September 30, 2016, as compared to the same periods in the prior year due to an increase in orders of the ChemoClave product.

Gross Margins

For the three and nine months ended September 30, 2016 gross margins were 52.8% and 53.1%, respectively, as compared to 53.8% and 52.70% for the three and nine months ended September 30, 2015, respectively. The 100 basis point decrease in gross margin for the three months ended September 30, 2016, as compared to the same period in the prior year was primarily due to increased spending on freight and labor to ensure higher customer service levels. The 40 basis point increase in gross margin for the nine months ended September 30, 2016, as compared to the same period in the prior year was primarily due to favorable foreign exchange rates on our operations expenses due to the decline in the Mexican Peso and favorable product mix partially offset by the impact of certain manufacturing constraints in the earlier part of the year.

Selling, General and Administrative ("SG&A") Expenses

	Three months ended September 30,				Nine months ended September 30,			
	2016	2015	$ Change	% Change	2016	2015	$ Change	% Change
SG&A	$ 22.4	$ 20.2	$ 2.2	10.9%	$ 66.8	$ 60.7	$ 6.1	10.0%

SG&A expenses increased for the three months ended September 30, 2016, as compared to the same period in the prior year, primarily due to an increase of $0.5 million in dealer fees and $0.4 million in commissions, $0.4 million in legal expenses, $0.3 million in depreciation and amortization, and $0.3 million in foreign exchange losses, partially offset by $0.4 million in lower medical device excise taxes. The increases in dealer fees and commissions were related to an increase in revenue on which they are calculated. Legal expenses increased when compared to the prior year's comparable quarter due to increased general fees associated with our patents in the current year. The increase in depreciation and amortization was primarily driven by amortization of acquired intangible assets related to our acquisition of EXC Holding Corp ("EXC"). The increase in foreign exchange losses was due to the unfavorable fluctuation of exchange rates in the current period versus those of the prior year comparable period. The decrease in medical device excise tax expense was due to the elimination of the tax in the current period due to Congress temporarily suspending this tax for the 2016-2017 two-year period.

SG&A expenses increased for the nine months ended September 30, 2016, as compared to the same period in the prior year primarily due to an increase of $3.5 million in compensation, $1.2 million in higher dealer fees, and $0.8 million in commissions and $0.6 million in depreciation and amortization partially offset by $1.3 million in lower medical device excise taxes. The increase in compensation was in part due to filling positions that were open during 2015, additional employees retained as part of the acquired SwabCap product line, the general hiring and recruitment of new employees and increases in stock-based compensation issued to attract these employees. The explanations for the other changes in year-to-date SG&A expenses are the same as indicated above with respect to the three months ended September 30, 2016.

Research and Development ("R&D") Expenses

	Three months ended September 30,				Nine months ended September 30,			
	2016	2015	$ Change	% Change	2016	2015	$ Change	% Change
R&D	$ 3.7	$ 4.2	$ (0.5)	(11.9)%	$ 10.3	$ 11.7	$ (1.4)	(12.0)%

R&D expenses decreased for the three and nine months ended September 30, 2016, as compared to the same period in the prior year primarily due to lower R&D project expenses, including a decrease in project costs related to our Cogent™ 2-in-1 hemodynamic monitoring system, which received FDA 510(k) clearance during the second quarter of 2016.

Restructuring and Strategic Transaction Expenses

Restructuring and strategic transaction expenses were $2.8 million and $4.3 million for the three and nine months ended September 30, 2016, respectively and $3.4 million for the three and nine months ended September 30, 2015.

Restructuring charges

Restructuring charges were $0.4 million and $0.8 million for the three and nine months ended September 30, 2016, respectively. These charges were primarily related to residual expenses for the closure of our Slovakian manufacturing facility and we incurred $0.2 million related to other restructuring activities.

Restructuring charges were $2.3 million for the three and nine months ended September 30, 2015. These charges were 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 and the reorganization of our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs.

Strategic transaction expenses

Strategic transaction expenses were $2.4 million and $3.5 million for the three and nine months ended September 30, 2016, respectively, related to our pending acquisition of the HIS business, our second quarter 2016 acquisition of Tangent and transition expenses related to our acquisition of EXC.

Strategic transaction expenses were $1.1 million for the three and nine months ended September 30, 2015 related to the acquisition of EXC.

Gain on Sale of Building

We recognized a gain of $1.1 million during the third quarter of 2015 from the sale of one of our buildings in San Clemente to Dr. Lopez, a member of our Board of Directors.

Legal Settlements

For the three months ended September 30, 2015 we recorded a settlement award, net of legal fees and costs, of $5.3 million and for the nine months ended September 30, 2015 we recorded a net settlement charge of $1.8 million.

On September 23, 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us $8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement.

On April 2, 2015, an arbitrator ruled on a breach of contract claim between us and Hospira, awarding Hospira $8.2 million Canadian dollars ($6.5 million U.S. dollars). The arbitrator also ruled that we pay 75% of Hospira's legal fees and expenses, which were $0.7 million dollars. We have fully paid the above mentioned legal fees and expenses.

Bargain Purchase Gain

The bargain purchase gain recognized was $0.3 million and $1.5 million for the three and nine months ended September 30, 2016, respectively. During the second quarter of 2016, in connection with the Tangent acquisition, we immediately recognized a $1.1 million bargain purchase gain that represented the excess of the estimated fair market value of the identifiable tangible and intangible assets acquired and liabilities assumed, net of deferred tax assets over the total purchase consideration. The bargain purchase was driven by our ability to realize acquired deferred tax assets. During the three months ended September 30, 2016, we adjusted the bargain purchase gain for the recognition of additional deferred tax assets.

Other Income

Other income was $0.2 million and $0.4 million for the three and nine months ended September 30, 2016, respectively, as compared to $0.2 million and $1.0 million for the three and nine months ended September 30, 2015, respectively.

Income Taxes

Income taxes were accrued at an estimated effective tax rate of 18% and 25% for the three and nine months ended September 30, 2016, respectively, as compared to 35% and 31% for the three and nine months ended September 30, 2015, respectively.

The effective tax rate for the three and nine months ended September 30, 2016 differs from the federal statutory rate principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities, and included material discrete tax benefits related to the adoption of Accounting Standard Update ("ASU") No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.

The effective tax rate during the three and nine months ended September 30, 2016 included a material discrete tax benefit of $3.6 million and $6.6 million, respectively, related to the impact of ASU 2016-09, adopted during the second quarter of 2016. The income tax benefit was treated as a discrete item when determining the annual estimated effective tax rate. See Note 2: New Accounting Pronouncements in our accompanying condensed consolidated financial statements for additional information.

The effective tax rates for the three and nine months ended 2015 differs from the federal statutory rate principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities and material discrete tax benefits related to the impact of changes in estimates of tax reserves related to uncertainties in income taxes as a result of the favorable conclusion of recent federal and state examinations.

Liquidity and Capital Resources

During the first nine months of 2016, our cash, cash equivalents and short and long-term investment securities increased by $52.2 million from $377.4 million at December 31, 2015 to $429.6 million at September 30, 2016.

Cash Flows from Operating Activities

Our cash provided by operations for the nine months ended September 30, 2016 was $68.7 million. Net income plus adjustments for non-cash net expenses contributed $79.0 million to cash provided by operations, and cash used by changes in operating assets and liabilities was $10.3 million. The changes in operating assets and liabilities included a $7.3 million decrease in accrued liabilities, a $6.6 million increase in inventories, a $2.2 million increase in prepaid expenses and other assets, and a $1.6 million decrease in accounts payable, partially offset by a $4.7 million increase in accounts receivable and $2.7 million in net changes to income taxes and deferred income taxes. The decrease in accrued liabilities was primarily due to the pay-out of fiscal year 2015 accrued bonuses in February of 2016, the payment of accrued restructuring charges related to the closure of our Slovakian manufacturing facility and the payment of acquisition-related accruals from our 2015 EXC acquisition. The increase in inventories was primarily due to building finished good safety stock, to support better customer deliveries, raw materials related to our Slovakia plant closure, and related transfer to our Mexico plant, and inventory associated with the acquired SwabCap product-line. The increase in prepaid expenses and other assets was primarily due to repayment of state aid and interest related to the closure of our Slovakian manufacturing facilities. The decrease in accounts payable was a result of the timing of disbursements. The increase in accounts receivable was due to an increase in revenue. The net changes in income taxes was a result of the timing of payments for cash tax purposes, which includes true-ups for 2015 overpayment and 2016 estimated taxes.

Our cash provided by operations for the nine months ended September 30, 2015 was $48.6 million, which includes a retrospective adjustment to include $6.2 million in excess tax benefits as an operating item due to the implementation of ASU 2016-09 during the second quarter of 2016. See Note 2: New Accounting Pronouncements in our accompanying condensed consolidated financial statements for additional information. Net income plus adjustments for non-cash net expenses contributed $62.5 million to cash provided by operations, which was partially offset by a $13.9 million decrease in cash provided by operating assets and liabilities, retrospectively adjusted for the impact of the aforementioned ASU. An $11.4 million increase in accounts receivable and $8.8 million increase in prepaid expenses and other were the largest changes in operating assets and liabilities. The increase in accounts receivable was primarily due to higher revenue and a slight increase in the number of days sales outstanding. The increase in prepaid expenses and other was primarily due to an $8.8 million receivable for a September 2015 legal settlement.

Cash Flows from Investing Activities

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

	Nine months ended September 30,			
	2016	2015	Change	
Investing Cash Flows:				
Purchases of property and equipment	$ (15,018)	$ (7,729)	$ (7,289)	(1)
Proceeds from sale of assets	1	3,592	(3,591)	(2)
Business acquisitions, net of cash acquired	(2,584)	—	(2,584)	(3)
Intangible asset additions	(861)	(778)	(83)	
Purchases of investment securities	(111,575)	(40,217)	(71,358)	(4)
Proceeds from sale of investment securities	45,429	70,293	(24,864)	(5)
Net cash provided by investing activities	$ (84,608)	$ 25,161	$ (109,769)	

(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) During the third quarter of 2015, we sold an office building for $3.6 million.
(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. During the second quarter of 2016, we acquired Tangent for $2.6 million in cash.
(4) During the third quarter of 2016, we amended our investment policy to allow for the purchase of securities with final maturities in excess of one year. Accordingly, we adjusted our investment strategy to take advantage of the higher yields available on these longer term securities. Our longer term securities have maturities up to three years.
(5) The proceeds from the sale of our investment securities decreased during the nine months of 2016, as compared to the comparable prior year period, due to certain corporate bonds that had larger investment balances and maturity dates within the first nine months ended September 30, 2015.

While we can provide no assurances, we estimate that our capital expenditures in 2016 will approximate $18.0 million to $20.0 million. We anticipate making additional investments in molds, machinery and equipment in our manufacturing operations in the U.S. and Mexico to support new and existing products and in information technology to benefit world-wide operations. Additionally, we are in the process of expanding our Mexico manufacturing plant for the anticipated increase in operations as a result of our Slovakian plant closure. We expect to use our cash and investments to fund our capital purchases. These planned amounts of spending are estimates and actual spending may substantially differ from these amounts.

Cash Flows from Financing Activities

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

	Nine months ended September 30,			
	2016	2015	Change	
Financing Cash Flows:				
Proceeds from exercise of stock options	$ 15,830	$ 10,974	$ 4,856	(1)
Proceeds from employee stock purchase plan	2,361	2,162	199	
Purchase of treasury stock	(17,155)	(1,523)	(15,632)	(2)
Net cash provided by financing activities	$ 1,036	$ 11,613	$ (10,577)	

(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, 2016, we purchased 174,885 shares of our common stock under our share purchase plan on the open market for $15.3 million. Additionally, our employees surrendered 19,717 shares of our common stock from vested restricted stock awards as consideration for approximately $1.8 million in minimum statutory withholding obligations paid on their behalf.

In July 2010, our Board of Directors approved a share purchase plan to purchase up to $40.0 million of our common stock. As of September 30, 2016, we had purchased $32.8 million of our common stock pursuant to this plan, leaving a balance of $7.2 million available for future purchases. This plan has no expiration date. We may purchase additional shares in future quarters and expect we would use our cash and investments to fund the share purchases.

We have a substantial cash and investment security position generated from profitable 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, buy back our common stock on an opportunistic basis and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation.

As of September 30, 2016, we had $18.4 million of cash and cash equivalents held in local currency by our foreign subsidiaries. If these funds were needed for our operations in the U.S., we would be required to accrue and pay U.S. taxes for a portion of any repatriated funds. However, we expect to permanently reinvest these funds outside of the U.S. and, based on our current plans, we do not presently anticipate a need to repatriate them to fund our U.S. operations.

We believe that our existing cash, cash equivalents and investment securities 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 illiquidity in our investment securities, 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.

Other Planned Uses of Capital and Financing

As mentioned above, on October 6, 2016, we entered into a Purchase Agreement to acquire the HIS business for total consideration of approximately $601.0 million in cash and 3.2 million shares of common stock, to be issued to Pfizer at the closing of the transaction. The cash portion of the consideration will be paid at closing from both cash on hand and senior secured credit facilities of up to $400 million consisting of a five-year term loan facility of $300 million and a revolving credit facility of $100 million that we intend to enter into at the closing of the transaction.

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

As of September 30, 2016, there were no material changes to our contractual obligations from the amounts reported in our 2015 Form 10-K, except with respect to our purchase obligations as follows (in thousands):

Contractual Obligations	2016
Purchase obligations	$ 5,337
	$ 5,337

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2015, we identified the critical accounting policies which affect our more significant estimates and assumptions used in preparing our consolidated financial statements. We have not changed these 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, including the HIS business, SwabCap (EXC) and Tangent; 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 U. S.; planned new orders for machinery and equipment; 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; the impact of our pending acquisition of the HIS business; future sales to and revenue from Pfizer and the importance of Pfizer to our growth; effect of the current relationship with Pfizer and the settlement with Hospira, including its effect on future revenue and our positioning with respect to new product introductions and market share; growth of our products in future years; design features of Clave products; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome and impact 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; plans to convert existing space; capital expenditures; our planned reinvestment of cash and cash equivalents held by our foreign subsidiaries; 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, 2015, 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

Financial Market Risk

We had a portfolio of government bonds, corporate bonds, U.S. Treasury securities, commercial paper and certificates of deposit of $106.6 million as of September 30, 2016. The securities are all “investment grade”, comprised of $8.8 million of pre-refunded municipal securities, $66.3 million of corporate bonds, $30.1 million of U.S. Treasury securities, $0.7 million of commercial paper and $0.8 million of certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of our portfolio and market conditions specific to the securities

in which we invest. Two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately $0.6 million to investment income based on the investment securities balance at September 30, 2016.

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, short-term investments, accounts receivable and accounts payable. In our European operations, our net Euro asset position at September 30, 2016 was approximately €21.8 million. We also have approximately €35.6 million in Euro denominated cash and investment accounts held by our corporate entity. A 10% change in the conversion of the Euro to the U.S. dollar for our cash and investments, accounts receivable, accounts payable and accrued liabilities from the September 30, 2016 spot rate would impact our consolidated amounts on these balance sheet items by approximately $6.4 million, or 1.6% 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. We currently do not hedge our foreign currency exposures.

Sales from the U.S. to foreign distributors are denominated in U.S. dollars, Euros, South African Rand and Australian dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, although principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2016 and our manufacturing spending from 2016 would have impacted 2016 cost of goods sold by approximately $0.6 million. To date, the change in the conversion of the Euro to the U.S. dollar has not had a material impact to our operating earnings.

Item 4. Controls and Procedures

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 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, 2016 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

We are from time to time involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

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, 2015, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC.

Risks Related to the Pending HIS Transaction with Pfizer

We may not be able to successfully or timely consummate the pending HIS transaction with Pfizer and such failure would adversely impact our business, our financial condition and the market price of our common stock.

On October 6, 2016, we entered into a Purchase Agreement with Pfizer to purchase the HIS business, consisting of IV pumps, solutions, and disposables and certain other assets of Pfizer, for a purchase price of $601 million in cash and 3,200,000 shares of our common stock to be issued to Pfizer at the closing of the transaction.

The completion of the pending HIS transaction is subject to the satisfaction of customary closing conditions set forth in the Purchase Agreement, including, among others: (1) the absence of any law or order or certain legal proceedings prohibiting the transaction, (2) the expiration or termination of applicable waiting periods and obtaining certain regulatory approvals under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and antitrust laws of certain other jurisdictions, (3) the accuracy of representations and warranties set forth in the Purchase Agreement and compliance with covenants set forth in the Purchase Agreement and (4) the absence of any material adverse effect with respect to the HIS business or our business. We will be unable to complete the pending HIS transaction until each of the conditions to closing is either satisfied or waived.

Risks and uncertainties related to the closing include, among others, the possible occurrence of any event, change or other circumstance that could give rise to the termination of the Purchase Agreement, the failure to consummate the HIS transaction because the conditions to the closing are not satisfied or waived by the parties, the risk that third-party approvals or consents required for the transaction are not obtained and that litigation may be filed which could prevent or delay the closing of the HIS transaction. Furthermore, under certain circumstances (involving our breach of certain obligations under the Purchase Agreement or our failure to close the pending HIS transaction), Pfizer can terminate the Purchase Agreement and require us to pay a termination fee of $75 million. In addition, we have incurred significant costs, expenses and fees for professional services and other transaction costs in connection with the pending HIS transaction, as well as the diversion of management resources, for which we will have received little or no benefit if the closing of the pending HIS transaction does not occur. For these and other reasons, our failure to complete the pending HIS transaction could have a material adverse impact on our business, financial condition and results of operations.

If we successfully consummate the pending HIS transaction, we may not realize the anticipated benefits of the transaction, which could adversely impact our business and our operating results.

The HIS transaction is a significant transaction for us and the HIS business is one in which we currently do not operate directly. The success of our business will depend, in part, on our ability to realize our anticipated benefits, opportunities and synergies from combining the businesses of our company and the HIS business. We can provide no assurance that the anticipated benefits of the HIS transaction will be fully realized in the time frame anticipated or at all. We have limited prior history of integrating acquired companies or businesses into our operations, much less one of this size and complexity. Integrating the operations of the HIS business with that of our own will be a complex, costly and time-consuming process and the nature of a carve out acquisition makes it inherently more difficult to assume operations on closing day as well as to integrate activities, as certain systems, processes and people may not all transfer with the acquired business to support such activities. The integration process may disrupt the businesses and, if implemented ineffectively, would restrict the realization of the full expected benefits. The failure to meet the challenges involved in integrating the two businesses could cause an interruption of, or a loss of momentum in, the activities of the combined businesses and could adversely affect the results of operations of the combined businesses. Potential difficulties that may be encountered in the integration process include the following:

- challenges in preserving important strategic customer and other third-party relationships of both businesses;
- the diversion of management's attention to integration matters;
- challenges in maintaining employee morale and retaining or attracting key employees;
- potential incompatibility of corporate cultures;
- changes in the combined business due to potential divestitures or requirements imposed by antitrust regulators;
- costs, delays and other difficulties consolidating corporate and administrative infrastructures and information systems and in implementing common systems and procedures including, in particular, our internal controls over financial reporting; and
- coordinating and integrating a geographically dispersed organization, including operations in jurisdictions we currently do not operate in.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. Achieving the anticipated benefits and the potential benefits underlying our reasons for the HIS business acquisition will depend on successful integration of the businesses. Because of the significance of the HIS business acquisition to us, our failure to successfully integrate the HIS business with that of our own could have a material adverse impact on our business, financial condition and results of operations.

We plan to use a significant portion of our cash on hand and incur a substantial amount of debt to finance the cash consideration portion and certain other amounts to be paid in connection with the HIS transaction, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness.

Following the consummation of the HIS transaction, we expect to have significantly less cash, cash equivalents and investment securities on hand than the approximately $372.4 million of cash, cash equivalents and investment securities we had as of September 30, 2016. Although our management believes that it will have access to cash sufficient to meet our business objectives and capital needs, the lessened availability of cash, cash equivalents and investment securities for a period of time following the consummation of the HIS transaction could constrain our ability to grow our business. In connection with the HIS transaction and the payment of the cash consideration, we also expect that at closing we will enter into senior credit facilities of up to $400 million. As a result, we will incur borrowing costs going forward. Our more leveraged financial position following the HIS transaction could make us vulnerable to general economic downturns and industry conditions, and place us at a competitive disadvantage relative to our competitors. In the event that we do not have adequate capital to maintain or develop our business, additional capital may not be available to us on a timely basis, on favorable terms, or at all. Moreover, our senior credit facilities may restrict how we may operate our business, including limiting our ability to engage in certain transactions and to incur additional indebtedness, and our business may be materially and adversely affected if these restrictions prevent us from implementing our business plan.

There have been no other material changes in the risk factors other than those mentioned above from those previously disclosed under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2015.

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

The following is a summary of our stock repurchasing activity during the third quarter of 2016:

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]
07/01/2016 — 07/31/2016	—	$ —	—	$ 7,169,000
08/01/2016 — 08/31/2016	—	$ —	—	$ 7,169,000
09/01/2016 — 09/30/2016	—	$ —	—	$ 7,169,000
Third quarter of 2016 total	—	$ —	—	$ 7,169,000

(1) Our common stock purchase plan, which authorized the repurchase of up to $40.0 million of our common stock, was authorized by our Board of Directors and publicly announced on July 19, 2010. 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

Exhibit 2.1	Stock and Asset Purchase Agreement, dated as of October 6, 2016, by and between Pfizer Inc., a Delaware corporation, and ICU Medical, Inc., a Delaware corporation. Incorporated by reference to Exhibit 2.1 to the Registrant's current report on Form 8-K filed October 13, 2016.
Exhibit 10.1	Debt Commitment Letter, dated as of October 6, 2016, by and among Wells Fargo Bank, National Association, Wells Fargo Securities, LLC, Barclays Bank PLC and ICU Medical, Inc., a Delaware corporation. Incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed October 13, 2016.
Exhibit 10.2	Form of Shareholders Agreement, by and between Pfizer Inc., a Delaware corporation, and ICU Medical, Inc., a Delaware corporation. Incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed October 13, 2016.
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
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

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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 9, 2016

Scott E. Lamb
Chief Financial Officer
(Principal Financial Officer)

Exhibit Index

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Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Exhibit 31.1

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 9, 2016

/s/ Vivek Jain

Chief Executive Officer

Exhibit 31.2

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 9, 2016

/s/ Scott E. Lamb

Chief Financial Officer

Exhibit 32.1

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, 2016 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 9, 2016

/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, 2016 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 9, 2016

/s/ Scott E. Lamb
Scott E. Lamb