ICU MEDICAL INC/DE
Form 10-Q
July 22, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended: June 30, 2011
Or

o 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.: 0-19974
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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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 x No o

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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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 July 10, 2011
Common	13,967,817

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

ICU Medical, Inc.

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

ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(Amounts in thousands, except per share data)

	June 30, 2011 (unaudited)	December 31, 2010 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$87,368	$78,850
Investment securities	33,444	14,507
Cash, cash equivalents and investment securities	120,812	93,357
Accounts receivable, net of allowance for doubtful accounts of $1,232 at June 30, 2011 and $742 at December 31, 2010	51,789	55,106
Inventories	49,372	44,056
Prepaid income taxes	4,468	687
Prepaid expenses and other current assets	7,443	9,574
Deferred income taxes	4,991	5,053
Total current assets	238,875	207,833
PROPERTY AND EQUIPMENT, net	87,561	83,545
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	13,780	14,806
DEFERRED INCOME TAXES	4,635	4,564
	$346,329	$312,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$12,308	$10,879
Accrued liabilities	14,471	14,629
Deferred revenue	—	254
Total current liabilities	26,779	25,762
COMMITMENTS AND CONTINGENCIES	—	—
DEFERRED INCOME TAXES	7,974	8,023
INCOME TAX LIABILITY	4,471	4,155
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 14,855 shares at June 30, 2011 and December 31, 2010, outstanding 13,963 shares at June 30, 2011 and 13,659 shares at December 31, 2010	1,486	1,486
Additional paid-in capital	56,377	56,502
Treasury stock, at cost — 892 shares at June 30, 2011 and 1,196 shares at December 31, 2010	(31,126)	(41,428)
Retained earnings	276,356	258,790
Accumulated other comprehensive income (loss)	4,012	(1,064)
Total stockholders' equity	307,105	274,286
	$346,329	$312,226

(1) December 31, 2010 balances were derived from audited consolidated financial statements.
The accompanying notes are an integral part of these consolidated financial statements.

ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Statements of Income
(Amounts in thousands, except per share data)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
REVENUES:				
Net sales	$77,661	$68,710	$148,999	$132,922
Other	135	152	268	303
TOTAL REVENUE	77,796	68,862	149,267	133,225
COST OF GOODS SOLD	41,595	36,735	78,440	74,171
Gross profit	36,201	32,127	70,827	59,054
OPERATING EXPENSES:				
Selling, general and administrative	19,730	19,372	42,593	39,027
Research and development	2,491	952	4,543	1,870
Legal settlement	—	—	(2,500)	—
Total operating expenses	22,221	20,324	44,636	40,897
Income from operations	13,980	11,803	26,191	18,157
OTHER INCOME	431	63	834	255
Income before income taxes	14,411	11,866	27,025	18,412
PROVISION FOR INCOME TAXES	(4,918)	(4,153)	(9,459)	(6,444)
NET INCOME	$9,493	$7,713	$17,566	$11,968
NET INCOME PER SHARE				
Basic	$0.69	$0.57	$1.28	$0.88
Diluted	$0.67	$0.56	$1.24	$0.86
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	13,852	13,469	13,772	13,665
Diluted	14,257	13,657	14,166	13,888

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

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ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)
(unaudited)

	Six months ended June 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$17,566	$11,968
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	9,052	8,602
Provision for doubtful accounts	437	97
Stock compensation	1,979	1,668
Loss (gain) on disposal of property and equipment	(56)	49
Bond premium amortization	399	947
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	3,908	(1,970)
Inventories	(4,025)	(1,423)
Prepaid expenses and other assets	(1,373)	(1,784)
Accounts payable	1,286	(1,140)
Accrued liabilities	(599)	1,387
Deferred revenue	(254)	(2,283)
Prepaid and deferred income taxes	(2,857)	1,421
Net cash provided by operating activities	25,463	17,539
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(9,755)	(11,285)
Proceeds from sale of asset	—	893
Proceeds from insurance	2,781	—
Purchases of investment securities	(32,236)	(13,698)
Proceeds from sale of investment securities	12,900	44,166
Net cash provided (used) by investing activities	(26,310)	20,076
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	4,572	103
Proceeds from employee stock purchase plan	909	747
Tax benefits from exercise of stock options	2,717	58
Purchase of treasury stock	—	(28,648)
Net cash provided (used) by financing activities	8,198	(27,740)
Effect of exchange rate changes on cash	1,167	(3,521)
NET INCREASE IN CASH AND CASH EQUIVALENTS	8,518	6,354
CASH AND CASH EQUIVALENTS, beginning of period	78,850	51,248
CASH AND CASH EQUIVALENTS, end of period	$87,368	$57,602
NON-CASH INVESTING ACTIVITIES		
Accrued liabilities for property and equipment	$262	$354

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

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ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Income
(Amounts in thousands)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net income	$9,493	$7,713	$17,566	$11,968
Other comprehensive income (loss), net of tax of $(47) and $(154) for the three months ended June 30, 2011 and 2010, respectively and $129 and $956 for the six months ended June 30, 2011 and 2010, respectively:				
Foreign currency translation adjustment	1,207	(4,507)	5,076	(6,014)
Comprehensive income	$10,700	$3,206	$22,642	$5,954

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

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ICU Medical, Inc.
Notes to Condensed Consolidated Financial Statements
Three and Six Months Ended June 30, 2011 and 2010
(Amounts in tables in thousands, except per share data)
(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 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 (the "Company"), filed with the SEC for the year ended December 31, 2010.

The Company operates in one business segment engaged in the development, manufacturing and sale of innovative medical technologies used in I.V. therapy, oncology and critical care applications. The Company's devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly owned and included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements:

In June 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-05 for Comprehensive Income (Topic 220): "Presentation of Comprehensive Income". This Update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This Update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholder's equity, which is how the Company presented such components in its Annual Report on Form 10-K for the year ended December 31, 2010. This Update is effective for interim and annual periods beginning after December 15, 2011 and is not expected to have a material effect on our results of operations, but will change the presentation of our financial statements.

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-04 for Fair Value Measurement (Topic 820): "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in
U.S. GAAP and IFRSs". This Update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this Update are effective for interim and annual periods beginning after December 15, 2011.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06 for Fair Value Measurements and Disclosures (Topic 820): "Improving Disclosures about Fair Value Measurements". This Update requires new disclosures for transfers in and out of Level 1 and 2 and activity in Level 3. This Update also clarifies existing disclosures for level of disaggregation and about inputs and valuation techniques. The new disclosures are effective for interim and annual periods beginning after December 15, 2009, except for the Level 3 disclosures, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within

those years. The Company had no Level 3 investments in the fiscal year beginning after December 15, 2010, and was therefore not impacted by this new pronouncement in the three and six months ended June 30, 2011.

Note 3: Legal Settlement:

In February 2011, the Company reached a settlement in its litigation against a law firm that formerly represented the Company in patent litigation matters, representing reimbursement of legal fees previously paid to the firm. Under the terms of the settlement, the Company received $2.5 million and this amount is included as a credit in operating expenses on the Condensed Consolidated Statement of Income for the six months ended June 30, 2011.

Note 4: Exit Activity from Italy Facility:

The Company’s new plant in Slovakia will serve our European product distribution. Product assembly previously

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done in the Company's Italy facility is now done in its Slovakia plant. As a result of this, the Company had termination costs to certain manufacturing and operations employees from the Italy facility. The product assembly transition from the Company's Italy plant to the Slovakia plant was completed in March 2011. The Italy facility continues to support sales in Europe. In the six months ended June 30, 2011, the Company recorded $0.6 million in one-time termination costs, $0.5 million in cost of goods sold and $0.1 million in sales, general and administrative expense. As of June 30, 2011, $0.3 million is accrued for these exit costs.

Note 5: Fair Value Measurement:

The Company's investment securities, which are carried at fair value and are considered available-for-sale, consist principally of certificates of deposit and tax-exempt state and municipal government debt. The Company has $3.2 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $30.3 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable market based inputs such as quoted prices, interest rates and yield curves.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis.

	Fair value measurements at June 30, 2011 using			
	Total carrying value at June 30, 2011	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$33,444	$3,160	$30,284	$—
	$33,444	$3,160	$30,284	$—

	Fair value measurements at December 31, 2010 using			
	Total carrying value at December 31, 2010	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$14,507	$2,820	$11,687	$—
	$14,507	$2,820	$11,687	$—

The Company had no Level 3 investments for the three and six months ended June 30, 2011. The following table presents the change in the fair values for Level 3 items for the three and six months ended June 30, 2010:

Level 3 changes in fair value (pre-tax):

	Three months ended June 30, 2010	Six months ended June 30, 2010
Beginning balance	$900	$900
Transfer into Level 3	—	—
Sales	(150)	(150)
Unrealized holding loss, included in other comprehensive income	—	—

Ending balance	$750	$750

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Note 6: Investment Securities:

The Company's investment securities consist of certificates of deposit 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 income in the shareholders' equity section of the Company's balance sheets. The Company had no gross unrealized gains or losses on available-for-sale securities at June 30, 2011 or December 31, 2010. The scheduled maturities of the debt securities are between 2011 and 2037 and are all callable within one year. The investment securities consist of the following at June 30, 2011 and December 31, 2010:

	June 30, 2011	December 31, 2010
Federal tax-exempt debt securities	$30,284	$11,687
Certificates of deposit	3,160	2,820
	$33,444	$14,507

Note 7: Inventories:

Inventories consisted of the following:

	June 30, 2011	December 31, 2010
Raw material	$26,270	$22,805
Work in process	4,224	3,806
Finished goods	18,878	17,445
Total	$49,372	$44,056

Note 8: Property and Equipment:

Property and equipment consisted of the following:

	June 30, 2011	December 31, 2010
Machinery and equipment	$70,150	$62,680
Land, building and building improvements	62,119	57,810
Molds	22,808	22,521
Computer equipment and software	16,544	14,613
Furniture and fixtures	2,241	2,107
Construction in progress	6,932	9,866
Total property and equipment, cost	180,794	169,597
Accumulated depreciation	(93,233)	(86,052)
Net property and equipment	$87,561	$83,545

Note 9: 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 (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 7,000 and 922,000 for the three months ended June 30, 2011 and 2010, respectively and 145,000 and 748,000 for the six months ended June 30, 2011 and 2010, respectively.

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The following table presents the calculation of net earnings per common share ("EPS") — basic and diluted.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net income	$9,493	$7,713	$17,566	$11,968
Weighted average number of common shares outstanding (for basic calculation)	13,852	13,469	13,772	13,665
Dilutive securities	405	188	394	223
Weighted average common and common equivalent shares outstanding (for diluted calculation)	14,257	13,657	14,166	13,888
EPS — basic	$0.69	$0.57	$1.28	$0.88
EPS — diluted	$0.67	$0.56	$1.24	$0.86

Note 10: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 40% and 41% of total revenue for the three months ended June 30, 2011 and 2010, respectively and 41% and 40% of total revenue for the six months ended June 30, 2011 and 2010, respectively. As of June 30, 2011 and December 31, 2010, the Company had accounts receivable from Hospira of 32% and 43% of consolidated accounts receivable, respectively.

Note 11: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 35% in the first half of 2011 and 2010.

Note 12: Commitments and Contingencies:

The Company is from time to time involved in various legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the legal proceedings in which the Company is involved will not likely have a material adverse impact on the Company's financial position or results of operations.

In the normal course of business, the Company has agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company's products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor does it presently expect to incur, any liability for indemnification.

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

We are a leader in the development, manufacture and sale of innovative medical technologies used in I.V. therapy, oncology and critical care applications. Our products improve patient outcomes by helping prevent bloodstream infections, protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitor the hemodynamic status of critical care patients. Our complete product line includes custom I.V. systems, closed delivery systems for hazardous drugs, needleless I.V. connectors, catheters and cardiac monitoring systems.

Business Overview

In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom infusion sets, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices beyond the CLAVE, a one-piece, needleless I.V. connection device.

One of our strategies has been to acquire new product lines. For example, in August 2009, we purchased the commercial rights and physical assets of Hospira's critical care product line, which resulted in our control over all aspects of this critical care product line, including production, sales, marketing, customer contracting and distribution. We had previously manufactured for sale, exclusively to Hospira, its critical care products. Pursuant to the prior arrangements, Hospira retained commercial responsibility for the products that we manufactured, including sales to end customers, marketing, pricing, distribution, customer contracts, customer service and billing. We had little ability to directly influence Hospira's sales and marketing efforts, and our sales under this arrangement were subject to fluctuations over which we had little control. The purchase of Hospira's critical care line has resulted in an increase in direct sales and sales to independent distributors but a decrease in sales to Hospira. There is no assurance that we will be successful in finding future acquisition opportunities.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. We have introduced a new line of oncology products including the Spiros male lure connector device, the Genie vial access device and ancillary products specifically designed for chemotherapy. We can provide no assurance that we will be able to successfully manufacture, market and sell these new products.

We are also expanding our business through increased sales to medical product manufacturers, independent distributors and through direct sales to the end users of our product. These expansions include our 2008 agreement with Premier, our recently awarded full-line critical care products agreement with Premier, our being named the single-source supplier of critical care products to Premier's ASCEND program, the extension of the term of our agreement with MedAssets, our recent entry into an agreement with Novation covering all of our critical care products and the growth of our internal sales and marketing group. Premier, MedAssets and Novation are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $48.0 million or 32% of total revenue for the first six months of 2011 and $100.6 million or 35% of total revenue for fiscal year 2010. CLAVE sales were $51.5 million or 34% of total revenue for the six months of 2011 and $98.4 million or 35% of total revenue for fiscal year 2010. Standard critical care sales were $25.8 million or 17% of total revenue in the first six months of 2011 and $50.4 million or 18% of total revenue for fiscal year 2010. We potentially face substantial increases in competition in our CLAVE business. Therefore, we are focusing on increasing product development, acquisition, sales and marketing efforts to custom products and other products that lend themselves to customization and new products in the U.S. and international markets.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be important for our growth. We currently manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. Additionally, as discussed above, prior to our acquisition of its critical care line, we previously manufactured Hospira's critical care products. For the first six months of 2011 and the years ended December 31, 2010 and 2009, our revenues from worldwide sales to Hospira were 41%, 44% and 53%, respectively, of total revenues. We expect revenues from sales of CLAVE products, custom infusion sets and new products to Hospira to remain a significant percentage of our revenues. Hospira has a significant share of the I.V. set market in the U.S. and provides us access to that market, and we expect that Hospira will be important to our growth for CLAVE, custom infusion sets, and our other products worldwide.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development; however, there is no assurance that we will be successful in implementing our growth strategy. The custom products market is small, when compared to the larger market of standard products, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see

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opportunity in this market. 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. An adverse change in our relationship with Hospira, or a deterioration of Hospira's position in the market, could have an adverse effect on us. 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.

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

	Three months ended June 30,		Six months ended June 30,		Fiscal Year Ended	
Product Line	2011	2010	2011	2010	2010	2009
CLAVE	34 %	34 %	34 %	35 %	35 %	37 %
Custom products	31 %	34 %	32 %	33 %	35 %	34 %
Standard critical care	17 %	20 %	17 %	20 %	18 %	18 %
Standard oncology products	8 %	3 %				