ICU MEDICAL INC/DE
Form 10-Q
April 22, 2011
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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: March 31, 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 o 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 April 10, 2011**
Common	13,774,276

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

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

	March 31, 2011 (unaudited)	December 31, 2010 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 71,114	$ 78,850
Investment securities	35,713	14,507
Cash, cash equivalents and investment securities	106,827	93,357
Accounts receivable, net of allowance for doubtful accounts of $991 at March 31, 2011 and $742 at December 31, 2010	50,587	55,106
Inventories	51,198	44,056
Prepaid income taxes		687
Prepaid expenses and other current assets	9,401	9,574
Deferred income taxes	4,939	5,053
Total current assets	222,952	207,833
PROPERTY AND EQUIPMENT, net	85,863	83,545
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	14,285	14,806
DEFERRED INCOME TAXES	4,617	4,564
	$ 329,195	$ 312,226
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 13,753	$ 10,879
Accrued liabilities	12,704	14,629
Deferred revenue	77	254
Income taxes payable	1,097	
Total current liabilities	27,631	25,762
COMMITMENTS AND CONTINGENCIES		
DEFERRED INCOME TAXES	7,987	8,023
INCOME TAX LIABILITY	4,155	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 March 31, 2011 and December 31, 2010, outstanding 13,732 shares at March 31, 2011 and 13,659 shares at December 31, 2010	1,486	1,486
Additional paid-in capital	57,222	56,502
Treasury stock, at cost 1,123 shares at March 31, 2011 and 1,196 shares at December 31, 2010	(38,954)	(41,428)
Retained earnings	266,863	258,790
Accumulated other comprehensive income (loss) income	2,805	(1,064)
Total stockholders equity	289,422	274,286
	$ 329,195	$ 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.

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Income

(Amounts in thousands, except per share data)

(unaudited)

	Three months ended March 31,	
	2011	**2010**
REVENUES:		
Net sales	$ 71,338	$ 64,212
Other	133	151
TOTAL REVENUE	71,471	64,363
COST OF GOODS SOLD	36,845	37,436
Gross profit	34,626	26,927
OPERATING EXPENSES:		
Selling, general and administrative	22,863	19,655
Research and development	2,052	918
Legal settlement	(2,500)	
Total operating expenses	22,415	20,573
Income from operations	12,211	6,354
OTHER INCOME	403	192
Income before income taxes	12,614	6,546
PROVISION FOR INCOME TAXES	(4,541)	(2,291)
NET INCOME	$ 8,073	$ 4,255
NET INCOME PER SHARE		
Basic	$ 0.59	$ 0.31
Diluted	$ 0.57	$ 0.30
WEIGHTED AVERAGE NUMBER OF SHARES		
Basic	13,692	13,863
Diluted	14,056	14,111

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)

	Three months ended March 31,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 8,073	$ 4,255
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,500	4,551
Provision for doubtful accounts	208	52
Stock compensation	978	823
Loss on disposal of property and equipment		50
Bond premium amortization	19	587
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired		
Accounts receivable	5,085	(1,793)
Inventories	(6,186)	2,997
Prepaid expenses and other assets	(252)	(1,158)
Accounts payable	2,764	(224)
Accrued liabilities	(2,091)	(1,042)
Deferred revenue	(278)	(1,203)
Prepaid and deferred income taxes	2,347	2,305
Net cash provided by operating activities	15,167	10,200
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(4,942)	(10,375)
Proceeds from sale of asset		893
Purchases of investment securities	(24,530)	(6,386)
Proceeds from sale of investment securities	3,304	20,672
Net cash provided (used) by investing activities	(26,168)	4,804
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	1,027	46
Proceeds from employee stock purchase plan	909	747
Tax benefits from exercise of stock options	280	29
Purchase of treasury stock		(23,976)
Net cash provided (used) by financing activities	2,216	(23,154)
Effect of exchange rate changes on cash	1,049	(198)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(7,736)	(8,348)
CASH AND CASH EQUIVALENTS, beginning of period	78,850	51,248
CASH AND CASH EQUIVALENTS, end of period	$ 71,114	$ 42,900

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 March 31,	
	2011	**2010**
Net income	$ 8,073	$ 4,255
Other comprehensive income (loss), net of tax of $176 and $1,110 for the three months ended March 31, 2011 and 2010, respectively:		
Foreign currency translation adjustment	3,869	(1,507)
Comprehensive income	$ 11,942	$ 2,748

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 Months Ended March 31, 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.

Subsequent to the issuance of the Company s first quarter 2010 10-Q, the Company reclassified $0.6 million in bond premium amortization, a noncash item, from investing activities in the consolidated statement of cash flows for the three months ended March 31, 2010 to a noncash item in cash flows from operating activities as an adjustment to reconcile net income to net cash provided by operating activities. The Company considers this an immaterial reclassification and has changed the first quarter of 2010 condensed consolidated statement of cash flows.

The Company operates in one business segment engaged in the development, manufacturing and sale of innovative medical technologies used in vascular 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 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 quarter ended March 31, 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 quarter ended March 31, 2011.

Note 4: Exit Activity from Italy Facility:

The Company s new plant in Slovakia will serve our European product distribution. Product assembly previously done in the Company s Italy facility will now be done its our 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 will continue to support sales in Europe. In the quarter ended March 31, 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 March 31, 2011, $0.5 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 $2.8 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $32.9 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable inputs.

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

			Fair value measurements at March 31, 2011 using					
	Total carrying value at March 31, 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	$	35,713	$	2,820	$	32,893	$	
	$	35,713	$	2,820	$	32,893	$	

The Company had no Level 3 investments for the quarter ended March 31, 2011.

			Fair value measurements at March 31, 2010 using					
	Total carrying value at March 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	$	41,114	$	8,855	$	32,259	$	
Trading securities		900						900
	$	42,014	$	8,855	$	32,259	$	900

The following tables summarize the change in the fair values for Level 3 items for the quarter ended March 31, 2010:

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

	Quarter ended March 31, 2010	
Beginning balance	$	900
Transfer into Level 3		
Sales		
Unrealized holding loss, included in other comprehensive income		
Ending balance	$	900

Note 6: Inventories:

Inventories consisted of the following:

	March 31, 2011	December 31, 2010
Raw material	$ 25,377	$ 22,805
Work in process	3,733	3,806
Finished goods	22,088	17,445
Total	$ 51,198	$ 44,056

Note 7: Property and Equipment:

Property and equipment consisted of the following:

	March 31, 2011	December 31, 2010
Machinery and equipment	$ 63,978	$ 62,680
Land, building and building improvements	61,156	57,810
Molds	22,802	22,521
Computer equipment and software	15,585	14,613
Furniture and fixtures	2,215	2,107
Construction in progress	10,008	9,866
Total property and equipment, cost	175,744	169,597
Accumulated depreciation	(89,881)	(86,052)
Net property and equipment	$ 85,863	$ 83,545

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Note 8: 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 135,000 and 472,000 for the three months ended March 31, 2011 and 2010, respectively.

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

	Three months ended March 31,	
	2011	**2010**
Net income	$ 8,073	$ 4,255
Weighted average number of common shares outstanding (for basic calculation)	13,692	13,863
Dilutive securities	364	248
Weighted average common and common equivalent shares outstanding (for diluted calculation)	14,056	14,111
EPS basic	$ 0.59	$ 0.31
EPS diluted	$ 0.57	$ 0.30

Note 9: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 41% of total revenue for both of the three months ended March 31, 2011 and 2010. As of March 31, 2011 and December 31, 2010, the Company had accounts receivable from Hospira of 37% and 43%, of consolidated accounts receivable, respectively.

Note 10: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 36% in the three months ended March 31, 2011 compared to 35% in the three months ended March 31, 2010. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of foreign and state income taxes, tax credits and deductions for domestic production activities.

Note 11: 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 vascular 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 and 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. Each of Premier, Med Assets and Novation is a U.S. healthcare purchasing network. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $24.1 million or 34% of total revenue for the first quarter of 2011 and $100.6 million or 35% of total revenue in 2010. CLAVE sales were $25.0 million or 35% of total revenue for the first quarter of 2011 and $98.4 million or 35% of revenue in 2010. Standard critical care sales were $12.7 million or 18% of total revenue in the first quarter of 2011 and $50.4 million or 18% of sales in 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 quarter 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 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.

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

	Quarter ended March 31,		Fiscal Year Ended	
Product Line	**2011**	**2010**	**2010**	**2009**
CLAVE	35%	36%	35%	37%
Custom products	34%	32%	35%	34%
Standard critical care	18%	19%	18%	18%
Standard oncology products	3%	2%	3%	2%
Other products/other revenue	10%	11%	9%	9%
Total	**100%**	**100%**	**100%**	**100%**

We sell our I.V. administration products to independent distributors, via direct sales and through agreements with Hospira and certain other medical product manufacturers. Most of our independent distributors handle the full line of our I.V. administration products. We also sell our I.V. administration and oncology products to Hospira pursuant to two agreements. Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, oncology products and the CLC2000. Under a 2001 agreement, we sell custom infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. We sell invasive monitoring and angiography to independent distributors and through direct sales. We also sell certain other products to a number of other medical product manufacturers.

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 such as our Hospira relationship, 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 revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer s products could have a material adverse effect on our operating results.

We have an ongoing effort to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These include the use of automated assembly equipment for new and existing products and use of larger molds and molding machines. In 2006, we centralized our proprietary molding in Salt Lake City and expanded our production facility in Mexico, which took over the majority of our manual assembly previously done in Salt Lake City. In January 2011, we completed an additional expansion of our production facility in Mexico. In late 2010, we completed construction of an assembly plant in Slovakia that will serve our European product distribution. Product shipments from this plant commenced in the fourth quarter of 2010. We may establish additional production facilities outside the U.S. There is no assurance that we will achieve success in establishing or expanding new manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel as a percentage of total channel product revenue were as follows:

	Quarter ended March 31,		Fiscal Year Ended	
Channel	**2011**	**2010**	**2010**	**2009**
Medical product manufacturers	40%	39%	41%	50%
Domestic distributors/direct	36%	37%	36%	29%

International customers	24%	24%	23%	21%
Total	**100%**	**100%**	**100%**	**100%**

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S. but subsequently used in products exported by