ICU MEDICAL INC/DE
Form 10-Q
July 30, 2008
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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: June 30, 2008

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 No. 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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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 Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes o No x

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

Class	**Outstanding at July 15, 2008**
Common	14,288,591

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share and per share data)

	6/30/08 (unaudited)	12/31/07 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 79,607	$ 7,873
Marketable securities	28,977	87,770
Cash, cash equivalents and marketable securities investments	108,584	95,643
Accounts receivable, net of allowance for doubtful accounts of $329 and $655 as of June 30, 2008 and December 31, 2007, respectively	29,633	26,115
Inventories	20,611	19,504
Prepaid income taxes	3,193	2,740
Prepaid expenses and other current assets	3,645	4,746
Deferred income taxes - current portion	4,143	4,509
Total current assets	169,809	153,257
PROPERTY AND EQUIPMENT, net	74,077	72,708
INTANGIBLE ASSETS, net	11,331	11,884
DEFERRED INCOME TAXES- non-current	2,689	2,432
INCOME TAXES RECEIVABLE- non-current	1,848	1,848
OTHER ASSETS	465	465
	$ 260,219	$ 242,594
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,234	$ 8,439
Accrued liabilities	14,136	13,036
Total current liabilities	21,370	21,475
DEFERRED INCOME TAXES - non-current portion	4,325	4,325
INCOME TAXES PAYABLE - non-current portion	3,190	2,890
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Convertible preferred stock, $1.00 par value- Authorized - 500,000 shares, issued and outstanding - none		
Common stock, $0.10 par value- Authorized 80,000,000 shares, issued 14,746,951 shares at June 30, 2008 and December 31, 2007	1,475	1,475
Additional paid-in capital	61,309	74,805
Treasury stock, at cost - 458,360 and 1,057,501 shares at June 30, 2008 and December 31, 2007, respectively	(17,754)	(40,776)
Retained earnings	184,674	177,004
Accumulated other comprehensive income, net of tax	1,630	1,396
Total stockholders equity	231,334	213,904
	$ 260,219	$ 242,594

(1) December 31, 2007 balances were derived from audited consolidated financial statements.

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 Income

(Amounts in thousands, except share and per share data)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2008	**2007**	**2008**	**2007**
REVENUES:				
Net sales	$ 48,382	$ 48,370	$ 92,053	$ 96,033
Other	210	520	1,193	1,690
TOTAL REVENUE	48,592	48,890	93,246	97,723
COST OF GOODS SOLD	27,788	28,252	54,671	57,869
Gross profit	20,804	20,638	38,575	39,854
OPERATING EXPENSES:				
Selling, general and administrative	13,685	11,504	26,793	23,503
Research and development	1,452	2,155	3,471	4,006
Total operating expenses, net	15,137	13,659	30,264	27,509
Income from operations	5,667	6,979	8,311	12,345
OTHER INCOME (EXPENSE)	1,139	(3,402)	2,695	5,997
Income before income taxes and minority interest	6,806	3,577	11,006	18,342
PROVISION FOR INCOME TAXES	(2,034)	(1,033)	(3,336)	(6,053)
MINORITY INTEREST				70
NET INCOME	$ 4,772	$ 2,544	$ 7,670	$ 12,359
NET INCOME PER SHARE				
Basic	$ 0.34	$ 0.18	$ 0.55	$ 0.85
Diluted	$ 0.33	$ 0.16	$ 0.53	$ 0.79
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	13,966,161	14,456,396	13,858,892	14,518,705
Diluted	14,381,185	15,534,568	14,387,683	15,572,663

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,	
	2008	**2007**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 7,670	$ 12,359
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	7,028	5,364
Provision for doubtful accounts	(282)	222
Minority interest		(70)
Stock compensation	882	310
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	(2,890)	(5,521)
Inventories	(969)	591
Prepaid expenses and other assets	565	(261)
Accounts payable	(1,252)	(1,345)
Accrued liabilities	1,037	5,296
Prepaid and deferred income taxes	(813)	526
Net cash provided by operating activities	10,976	17,471
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(7,122)	(14,171)
Cash paid for acquired assets		(3,224)
Proceeds from finance loan repayments	48	38
Purchases of marketable securities	(12,357)	(18,258)
Proceeds from sale of marketable securities	70,685	21,004
Net cash provided (used) by investing activities	51,254	(14,611)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	4,602	808
Proceeds from employee stock purchase plan	744	742
Tax benefits from exercise of stock options	3,849	238
Purchase of treasury stock		(8,613)
Net cash provided (used) by financing activities	9,195	(6,825)
Effect of exchange rate changes on cash	309	69
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	71,734	(3,896)
CASH AND CASH EQUIVALENTS, beginning of period	7,873	13,153
CASH AND CASH EQUIVALENTS, end of period	$ 79,607	$ 9,257

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,	
	2008	2007	2008	2007
Net income	$ 4,772	$ 2,544	$ 7,670	$ 12,359
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on investments	347		(288)	
Foreign currency translation adjustment	(214)	108	522	158
Comprehensive income	$ 4,905	$ 2,652	$ 7,904	$ 12,517

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

June 30, 2008

(Amounts in tables in thousands except share and 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 and reflect all adjustments, which consist 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 Company s 2007 Annual Report to Stockholders.

ICU Medical, Inc. (the Company), a Delaware corporation, operates principally in one business segment engaged in the development, manufacturing and marketing of disposable medical devices. The Company s devices are sold principally to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly or majority owned and included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements: In December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) 141R, Business Combinations . SFAS 141R amends the requirements for accounting for business combinations. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations the Company engages in will be recorded and disclosed following existing accounting principles until December 31, 2008.

Note 3: Fair Value Measurement: The Company adopted SFAS No. 157, Fair Value Measurements, (SFAS 157) as of January 1, 2008. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. This statement applies under other accounting pronouncements that require or permit fair value measurements. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of June 30, 2008:

		Fair value measurements at June 30, 2008 using		
	Total carrying value at June 30, 2008	**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	$ 28,977	$	$ 2,867	$ 26,110

The Company s marketable securities, all of which are considered available for sale, consist principally of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities that reset dividend or interest rates at auction, principally from between seven and forty-nine day intervals. The Company has $2.9 million of its marketable securities as Level 2 assets, which are pre-refund municipal securities and have observable inputs. The Company has $26.1 million of its marketable securities as Level 3 assets due to the unobservable inputs caused by the lack of liquidity in the recent auctions. The valuation of these securities was based on recommended fair values provided by our broker combined with internal analysis of interest rate spreads and credit quality. They are carried at fair value that resulted in a temporary impairment of $0.3 million as of June 30, 2008 which is reflected in Other Comprehensive Income in the Stockholders Equity section of the Condensed Consolidated Balance Sheet.

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The following tables summarize the change in the fair values for Level 3 items for the quarter and six months ended June 30, 2008:

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

	Quarter ended June 30, 2008	Six months ended June 30, 2008
Beginning balance	$ 61,540	$
Transfer into Level 3		87,770
Sales	(35,600)	(61,195)
Unrealized holding gain (loss), included in other comprehensive income	170	(465)
Ending balance	$ 26,110	$ 26,110

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 provides companies with an option to report selected financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date. SFAS 159 was effective for the Company on January 1, 2008. The Company s management did not elect to begin reporting any financial assets or liabilities at fair value upon adoption of SFAS 159. In addition, the Company s management did not elect to report at fair value any new financial assets or liabilities entered into for the quarter ended June 30, 2008.

Note 4: Inventories consisted of the following:

	6/30/08	12/31/07
Raw material	$ 15,072	$ 15,622
Work in process	2,558	1,712
Finished goods	2,981	2,170
Total	$ 20,611	$ 19,504

Note 5: Property and equipment consisted of the following:

	6/30/08	12/31/07
Machinery and equipment	$ 47,806	$ 45,503
Land, building and building improvements	50,289	48,546
Molds	15,870	14,029
Computer equipment and software	9,887	8,927
Furniture and fixtures	2,031	1,982
Construction in progress	4,946	4,900
Total property and equipment, cost	130,829	123,887
Accumulated depreciation	(56,752)	(51,179)
Net property and equipment	$ 74,077	$ 72,708

Note 6: 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, and were 415,024 and 1,078,172 for the quarters ended June 30, 2008 and 2007, respectively and 528,791 and 1,053,958 for the six months ended June 30, 2008 and 2007, respectively. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 1,815,000 and 20,000 for the quarters ended June 30, 2008 and 2007, respectively and 1,604,000 and 40,000 for the six months ended June 30, 2008 and 2007, respectively.

Note 7: Income Taxes: Income taxes were accrued at an effective tax rate of 30.3% in the first half of 2008 compared to 33.0% in the first half of 2007. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of state income taxes, state tax credits, tax exempt income and deductions for domestic production activities.

Note 8: Major Customers and Geographic Information: The Company had revenues equal to ten percent or more of total revenues from one customer, Hospira, Inc. Such revenues were 67% and 73% of total revenue for the quarters ended June 30, 2008 and 2007, respectively, and 66% and 74% for the six months ended June 30, 2008 and 2007, respectively.

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Note 9: Litigation Matters: In January 2007, the Company received $8.0 million in settlement of litigation against a law firm that formerly represented the Company in patent litigation matters. This is included in Other Income in the Condensed Consolidated Statements of Income for the six months ended June 30, 2007.

In June 2007, the Company recorded a charge of $4.8 million for a judgment against the Company for reimbursement of legal fees following the dismissal of the Company s claim of patent infringement. This is included in Other Income in the Condensed Consolidated Statements of Income for the quarter and six months ended June 30, 2007.

Note 10: Commitments and Contingencies: The Company is from time to time involved in various legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. The Company believes that the resolution of the legal proceedings in which it is currently involved will not have a material adverse effect on its 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 expect to incur, any liability for indemnification. Except for indemnification agreements, the Company does not have any off balance sheet arrangements .

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 proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter-related bloodstream infections and healthcare workers from exposure to infectious diseases through accidental needlesticks. We are also a leader in the production of custom I.V. systems and we incorporate our proprietary products into many of those custom I.V. systems. We are also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

Critical Accounting Policies

In our 2007 Annual Report on Form 10-K, 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

In December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) 141R, Business Combinations (SFAS 141R). SFAS 141R amends the requirements for accounting for business combinations. SFAS 141R will be effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations we engage in will be recorded and disclosed following existing accounting principles until December 31, 2008.

We have implemented all new accounting pronouncements that are in effect and that may impact our consolidated financial statements and do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our consolidated financial statements.

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom I.V. systems, 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.

Our largest customer is Hospira Inc. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In the first half of 2008 and the years ended 2007, 2006 and 2005, our revenues from worldwide sales to Hospira were 66%, 73%, 77% and 74%, respectively, of total revenues. We expect this percentage of revenue range will be maintained in the future as a result of sales of CLAVE products, custom products, new products and critical care products to Hospira. Hospira has a significant share of the I.V. set market in the U.S., and provides us access to that market. We expect that Hospira will be important to our growth for CLAVE, custom products, and our other products worldwide.

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We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We have patents covering the technology embodied in the CLAVE and intend to enforce those patents as appropriate. If we are not successful in enforcing our patents, competition from such products could adversely affect our market share and prices for our CLAVE products. Although overall pricing has been stable recently, the average price of our CLAVE products may decline in the future. There is no assurance that our current or future products will be able to successfully compete with products developed by others.

We are reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. Under one of our agreements with Hospira, we manufacture custom I.V. systems for sale by Hospira and jointly promote the products. In 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into the Manufacturing Commercialization and Development Agreement (MCDA) to produce their invasive monitoring, angiography products and certain other products they had manufactured at that facility. We also contract with group purchasing organizations and independent dealer networks for inclusion of our CLAVE, custom products and safe handling products used in markets, such as oncology, in the product offerings of those entities. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors, and through direct sales. Custom products, which include custom I.V., custom oncology and custom critical care products, accounted for approximately $32.0 million or 34% of total revenue in the first half of 2008. We expect continued increases in sales of custom products. We have recently introduced a number of new products: the TEGO for use in dialyses, and a line of oncology products including the SPIROS male luer connector device, the Genie vial access device and custom I.V sets and ancillary products specifically designed for oncology therapy. There is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

Custom products and new products will be of increasing importance to us in future years. We expect continued growth in our CLAVE products in the U.S., but at a modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. Growth for all of our products outside the U.S. could be substantial, although to date it has been relatively modest. Therefore, we are directing 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.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development in these markets.

There is no assurance that we will be successful in implementing our growth strategy. The custom products market is small, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity. Product development or acquisition efforts may not succeed, and even if we do develop or acquire 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 those risks, certain of those risks 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	**2008**	**2007**	**2008**	**2007**	**2007**	**2006**	**2005**
CLAVE	38%	39%	39%				