ICU MEDICAL INC/DE
Form 10-Q
October 23, 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: September 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 the definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

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 October 15, 2008**
Common	14,367,442

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ICU Medical, Inc.

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

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

	9/30/08 (unaudited)	12/31/07 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 61,575	$ 7,873
Marketable securities	55,820	87,770
Cash, cash equivalents and marketable securities investments	117,395	95,643
Accounts receivable, net of allowance for doubtful accounts of $292 and $655 as of September 30, 2008 and December 31, 2007, respectively	32,319	26,115
Inventories	19,156	19,504
Prepaid income taxes	2,487	2,740
Prepaid expenses and other current assets	4,603	4,746
Deferred income taxes - current portion	4,702	4,509
Total current assets	180,662	153,257
PROPERTY AND EQUIPMENT, net	73,067	72,708
INTANGIBLE ASSETS, net	10,987	11,884
DEFERRED INCOME TAXES- non-current	2,689	2,432
INCOME TAXES RECEIVABLE- non-current	1,848	1,848
OTHER ASSETS	465	465
	$ 269,718	$ 242,594
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,585	$ 8,439
Accrued liabilities	14,717	13,036
Total current liabilities	22,302	21,475
DEFERRED INCOME TAXES - non-current portion	4,325	4,325
INCOME TAXES PAYABLE - non-current portion	3,126	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 September 30, 2008 and December 31, 2007	1,475	1,475
Additional paid-in capital	60,191	74,805
Treasury stock, at cost - 379,509 and 1,057,501 shares at September 30, 2008 and December 31, 2007, respectively	(14,656)	(40,776)
Retained earnings	192,319	177,004
Accumulated other comprehensive income, net of tax	636	1,396
Total stockholders equity	239,965	213,904
	$ 269,718	$ 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 September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
REVENUES:				
Net sales	$ 54,374	$ 44,379	$ 146,427	$ 140,412
Other	361	489	1,554	2,179
TOTAL REVENUE	54,735	44,868	147,981	142,591
COST OF GOODS SOLD	29,788	25,502	84,459	83,371
Gross profit	24,947	19,366	63,522	59,220
OPERATING EXPENSES:				
Selling, general and administrative	13,571	11,485	40,364	34,988
Research and development	857	2,234	4,328	6,240
Total operating expenses, net	14,428	13,719	44,692	41,228
Income from operations	10,519	5,647	18,830	17,992
OTHER INCOME	994	1,379	3,689	7,376
Income before income taxes and minority interest	11,513	7,026	22,519	25,368
PROVISION FOR INCOME TAXES	(3,868)	(2,319)	(7,204)	(8,372)
MINORITY INTEREST				70
NET INCOME	$ 7,645	$ 4,707	$ 15,315	$ 17,066
NET INCOME PER SHARE				
Basic	$ 0.53	$ 0.33	$ 1.09	$ 1.18
Diluted	$ 0.52	$ 0.31	$ 1.06	$ 1.10
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	14,327,213	14,346,766	14,016,145	14,460,760
Diluted	14,685,127	15,290,208	14,481,383	15,457,815

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)

	Nine months ended September 30,	
	2008	**2007**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 15,315	$ 17,066
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	10,714	8,428
Provision for doubtful accounts	(297)	386
Minority interest		(70)
Stock compensation	1,357	583
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	(6,125)	(1,346)
Inventories	301	(1,297)
Prepaid expenses and other assets	(631)	(581)
Accounts payable	(836)	(1,335)
Accrued liabilities	1,698	5,313
Prepaid and deferred income taxes	(162)	2,815
Net cash provided by operating activities	21,334	29,962
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(9,685)	(19,128)
Cash paid for acquired assets		(3,224)
Proceeds from finance loan repayments	60	68
Purchases of marketable securities	(42,064)	(19,210)
Proceeds from sale of marketable securities	73,543	27,185
Net cash provided (used) by investing activities	21,854	(14,309)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	5,035	1,599
Proceeds from employee stock purchase plan	1,373	1,402
Tax benefits from exercise of stock options	4,293	434
Purchase of treasury stock		(25,734)
Net cash provided (used) by financing activities	10,701	(22,299)
Effect of exchange rate changes on cash	(187)	299
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	53,702	(6,347)
CASH AND CASH EQUIVALENTS, beginning of period	7,873	13,153
CASH AND CASH EQUIVALENTS, end of period	$ 61,575	$ 6,806

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 September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Net income	$ 7,645	$ 4,707	$ 15,315	$ 17,066
Other comprehensive loss, net of tax:				
Unrealized loss on investments	(32)		(320)	
Foreign currency translation adjustment	(962)	552	(440)	710
Comprehensive income	$ 6,651	$ 5,259	$ 14,555	$ 17,776

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

September 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 September 30, 2008:

		Fair value measurements at September 30, 2008 using		
	Total carrying value at September 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	$ 55,820	$	$ 32,241	$ 23,579

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 $32.2 million of its marketable securities as Level 2 assets, which are pre-refunded municipal securities and have observable inputs. The Company has $23.6 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 September 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 nine months ended September 30, 2008:

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

	Quarter ended September 30, 2008	Nine months ended September 30, 2008
Beginning balance	$ 26,110	$
Transfer into Level 3		87,770
Sales	(2,525)	(63,720)
Unrealized holding loss, included in other comprehensive income	(6)	(471)
Ending balance	$ 23,579	$ 23,579

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 September 30, 2008.

Note 4: **Inventories** consisted of the following:

	9/30/08	12/31/07
Raw material	$ 13,694	$ 15,622
Work in process	2,884	1,712
Finished goods	2,578	2,170
Total	$ 19,156	$ 19,504

Note 5: **Property and equipment** consisted of the following:

	9/30/08	12/31/07
Machinery and equipment	$ 49,877	$ 45,503
Land, building and building improvements	50,513	48,546
Molds	16,525	14,029
Computer equipment and software	9,942	8,927
Furniture and fixtures	1,993	1,982
Construction in progress	3,296	4,900
Total property and equipment, cost	132,146	123,887
Accumulated depreciation	(59,079)	(51,179)

Net property and equipment	$	73,067	$	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 357,914 and 943,442 for the quarters ended September 30, 2008 and 2007, respectively and 465,238 and 997,055 for the nine months ended September 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 1,423,000 and 152,000 for the quarters ended September 30, 2008 and 2007, respectively and 1,619,000 and 40,000 for the nine months ended September 30, 2008 and 2007, respectively.

Note 7: **Income Taxes:** Income taxes were accrued at an effective tax rate of 32% in the first nine months of 2008 compared to 33% in the first nine months 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.

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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 71% and 72% of total revenue for the quarters ended September 30, 2008 and 2007, respectively, and 68% and 73% for the nine months ended September 30, 2008 and 2007, respectively.

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 nine months ended September 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 nine months ended September 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.

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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 nine months of 2008 and the years ended 2007, 2006 and 2005, our revenues from worldwide sales to Hospira were 68%, 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.

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 $51.2 million or 35% of total revenue in the first nine months 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 September 30,		Nine months ended September 30,		Fiscal Year Ended	
Product Line	**2008**	**2007**	**2008**	**2007**	**2007**	**2006**
CLAVE	37%	40%	39%	38%	38%	34%
Custom products	35%	31%	35%	31%	31%	28%
Critical care	19%	22%	18%	24%	23%	25%
Other products	8%	6%	7%	5%	7%	12%
License, royalty and revenue share	1%	1%	1%	2%	1%	1%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

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We sell our I.V. administration products to independent distributors, and through direct sales and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We sell our invasive monitoring, angiography and I.V. administration products through three agreements with Hospira (the Hospira Agreements). Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors and the CLC2000. Under a 2001 agreement, we sell custom I.V. systems to Hospira. 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. Under the 2005 MCDA, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. The terms of the MCDA extend to 2025. 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 program 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 2007, we began a significant initiative to improve production processes, called the ICU Production System or IPS , which we believe, over time, will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and started it in our Salt Lake City facility in 2008. We may establish additional production facilities outside the U.S. We had plans to begin building a manufacturing facility in China in 2008, but those plans have been put on hold. There is no assurance as to the benefits of IPS or our success in establishing manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel were as follows:

	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended	
Channel	**2008**	**2007**	**2008**	**2007**	**2007**	**2006**
Medical product manufacturers	67%	70%	67%	72%	71%	76%
Domestic distributors/direct	18%	16%	18%	15%	16%	14%
International customers	15%	14%	15%	13%	13%	10%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S., but used in I.V. products manufactured by Hospira and exported. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers.

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Quarter-to-quarter comparisons: We present summarized income statement data in Item 1- Financial Statements. The following table shows, for the year 2007, the third quarters of 2008 and 2007 and the first nine months of 2008 and 2007, the percentages of each income statement caption in relation to total revenues.

	Year	Three months ended September 30,		Nine months ended September 30,	
	2007	**2008**	**2007**	**2008**	**2007**
Revenue					
Net sales	99%	99%	99%	99%	98%
Other	1%	1%	1%	1%	2%
Total revenues	100%	100%	100%	100%	100%
Gross profit	42%	46%	43%	43%	42%
Selling, general and administrative expenses	24%	25%	26%	27%	25%
Research and development expenses	5%	2%	5%	3%	4%
Total operating expenses	29%	27%	31%	30%	29%
Income from operations	13%	19%	12%	13%	13%
Other income	5%	2%	3%	2%	5%
Income before income taxes and minority interest	18%	21%	15%	15%	18%
Income taxes	6%	7%	5%	5%	6%
Minority interest	%	%	%	%	%
Net income	12%	14%	10%	10%	12%

Quarterly results: The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This may cause seasonal fluctuations in our business. 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.

Quarter Ended September 30, 2008 Compared to the Quarter Ended September 30, 2007

Revenues were $54.7 million in the third quarter of 2008 compared to $44.9 million in the third quarter of 2007.

Distribution channels: Net U.S. sales to Hospira in the third quarter of 2008 were $35.7 million, compared to net sales of $30.4 million in the third quarter of 2007. The $5.3 million increase was primarily comprised of a $2.2 million increase in custom product sales, $1.8 million increase in CLAVE sales and $0.7 million increase in critical care sales. The increase in custom product sales was from higher unit sales in custom I.V. systems, custom critical care

and custom oncology. The increase in CLAVE and critical care was from higher unit sales. We expect comparable sales to Hospira for the full year of 2008 compared to 2007 because the growth in custom I.V. systems and new oncology product sales should be offset by the decline in critical care and custom critical care product sales.

Net sales to domestic distributors/direct (including Canada) in the third quarter of 2008 and 2007 were $9.5 and $7.3 million, respectively, an increase of $2.2 million or 30%. This increase was primarily from increased sales in custom products of $1.6 million and CLAVE of $0.4 million. Both increases are primarily from increased unit volume. We expect that sales to domestic distributors/direct in 2008 compared to 2007 will increase principally from growth in custom and CLAVE products, with modest sales growth in other products, including new products, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were $8.2 million in the third quarter of 2008, compared to $6.0 million in the third quarter of 2007, an increase of $2.2 million or 37%. This increase resulted primarily from $1.2 million of increased custom product sales and $0.4 million of increased CLAVE sales. Both increases are from increased unit volume. We expect increases in sales in 2008 compared to 2007 to international customers across most areas and principal product lines, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE products were $20.4 million in the third quarter of 2008 compared to $17.7 million in the third quarter of 2007, an increase of $2.7 million or 15%. This increase was in all distribution channels.

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Net sales of custom products, which includes custom I.V. systems, custom critical care and custom oncology sales, were $19.1 million in the third quarter of 2008 compared to $14.0 million in the third quarter of 2007. This increase was comprised of increased sales of custom oncology products of $3.0 million, custom I.V. systems of $1.1 million and custom critical care products of $1.0 million. The increases in custom revenue were primarily due to higher unit sales.

Critical care product sales were $10.4 million in the third quarter of 2008 compared to $9.7 million in the third quarter of 2007, from higher unit volume.

Our new oncology product sales, including custom oncology, were $4.1 million in the third quarter of 2008 compared to $0.3 million in the third quarter of 2007.

Other revenue consists of license, royalty and revenue share income and was approximately $0.4 million and $0.5 million in the third quarter of 2008 and 2007, respectively. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margin for the third quarter of 2008 and 2007 was 46% and 43%, respectively. The margin improvement is attributable to a favorable product mix, improved efficiencies and productivity gains at our Mexico manufacturing facility, offset by an increase in raw material and transportation costs and by a decrease in pricing for critical care.

We estimate our gross margin in 2008 will approximate 43%. However, there is no assurance this expectation will be realized.

Selling, general and administrative expenses **(SG&A)** were $13.6 million and 25% of revenues in the third quarter of 2008, compared with $11.5 million and 26% in the third quarter of 2007, or an increase of $2.1 million. Increased sales and marketing promotional costs of $0.7 million, outside service costs of $0.5 million and legal expense of $0.3 million accounted for the majority of the increase. We expect SG&A in 2008 to approximate 26% to 27% of revenue. There is no assurance that this expectation will be realized.

Research and development expenses **(R&D)** were $0.9 million or two percent of revenue in the third quarter of 2008 compared to $2.2 million or five percent of revenue in the third quarter of 2007. The decrease was mainly due to increased focus on our core projects during the quarter. We expect R&D in 2008 to be approximately three percent of revenue, although there is no assurance that this expectation will be realized.

Other income was $1.0 million of income in the third quarter of 2008 and $1.4 million in the third quarter of 2007. Interest income was $0.5 million in the third quarter of 2008 and $1.1 million in the third quarter of 2007,

respectively. The decrease in interest income is primarily due to lower interest rates.

Income taxes were accrued at an effective tax rate of 34% in the third quarter of 2008 compared to 33% in the third quarter of 2007. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of state income taxes, state credits, tax exempt incomes and deductions for domestic production activities. We expect our effective tax rate to be approximately 31% - 32% in 2008 before fourth quarter discrete tax items that should lower our effective tax rate to be approximately 22% - 24%. The majority of the discrete tax benefits expected in the fourth quarter will be attributable to tax credits for research and development as a result of the recent enactment of federal legislation. The remainder will be attributable to the realization of a non-recurring realization of tax benefits related to intangible assets. There is no assurance that this expectation will be realized.

Nine Months Ended September 30, 2008 Compared to the Nine Months Ended September 30, 2007

Revenues were $148.0 million in the first nine months of 2008 compared to $142.6 million in the first nine months of 2007.

Distribution channels: Net U.S. sales to Hospira in the first nine months of 2008 were $95.4 million, compared to net sales of $98.4 million in the first nine months of 2007. This $3.0 million decrease was primarily comprised of $6.7 million of decreases in critical care sales due to lower prices charged under the MCDA and lower unit sales of certain critical care products, partially offset by increased sales of $1.6 million in custom products, $1.0 million in CLAVE and $0.7 million in oncology products. Custom product sales, which include custom I.V. systems, custom critical care and custom oncology sales, to Hospira approximated $24.7 million in the first nine months of 2008 compared to $23.0 million in the first nine months of 2007. Increased sales of custom I.V. sets and new custom oncology products were partially offset by a $1.0 million decrease in custom critical care sales.

Net sales to domestic distributors/direct (including Canada) in the first nine months of 2008 and 2007 were $26.5 and $21.3 million, respectively, an increase of $5.2 million or 24%. This increase was primarily from increased sales of custom products of $3.8 million, which includes increased sales of custom oncology of $0.5 million and CLAVE of $1.2 million. Both increases are primarily from increased unit volume.

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Net sales to international customers (excluding Canada) were $21.7 million in the first nine months of 2008, compared to $18.6 million in the first nine months of 2007, an increase of $3.1 million. This increase was primarily from increased custom product sales of $1.4 million, new oncology sales of $0.7 million and increased CLAVE sales of $0.6 million. The growth was primarily attributable to increased sales in Europe and the Pacific Rim.

Product and other revenue: Net sales of CLAVE products were $57.1 million in the first nine months of 2008 compared to $54.1 million in the first nine months of 2007. The increase was from increased sales in all channels, primarily from increased unit sales.

Net sales of custom products, which includes custom I.V. systems, custom critical care and custom oncology sales, were $51.2 million in the first nine months of 2008 compared to $44.3 million in the first nine months of 2007. New sales of custom oncology products of $5.5 million, combined with increased sales in custom I.V. systems of $2.0 million, were partially offset by a decline in sales of custom critical care products of $0.6 million. The increase in custom I.V. system revenue was primarily due to higher unit sales. The decrease in custom critical care products was primarily due to lower unit sales and lower prices under the MCDA.

Critical care product sales were $26.7 million in the first nine months of 2008 compared to $33.3 million in the first nine months of 2007, a decrease of $6.6 million. This decrease was due to lower unit volume and lower prices under the MCDA. These sales are predominately controlled by Hospira and there is no assurance Hospira will be able to stop the decline in sales of critical care products.

Our new oncology product sales, including custom oncology, were $7.8 million in the first nine months of 2008 compared to $0.5 million in the first nine months of 2007.

Other revenue consists of license, royalty and revenue share income and was approximately $1.6 million in the first nine months of 2008 and $2.2 million in the first nine months of 2007.

Gross margin for the first nine months of 2008 and 2007 was 43% and 42%, respectively. The margin improvement is attributable to a favorable product mix, improved efficiencies and productivity gains at our Mexico manufacturing facility, and an increase in production volumes, offset by an increase in raw material and transportation costs and by a decrease in pricing for critical care.

Selling, general and administrative were $40.4 million and 27% of revenues in the first nine months of 2008, compared with $35.0 million and 25% in the first nine months of 2007. This increase was primarily from increased compensation and benefit expenses of $2.0 million, stock compensation expense of $0.8 million, sales and marketing promotional costs of $1.4 million, outside services of $1.1 million and travel of $0.7 million, offset by lower legal costs of $0.7 million and bad debt recoveries of $0.7 million. The higher compensation and benefits costs were primarily in incentive compensation and higher salary costs, including six new sales personnel. The lower legal fees

are primarily due to the conclusion of two legal actions in the first half of 2007.

Research and development expenses were $4.3 million or three percent of revenue in the first nine months of 2008 compared to $6.2 million or four percent of revenue in the first nine months of 2007. The decrease was mainly due to increased focus on our core projects in 2008.

Other income was $3.7 million in the first nine months of 2008 and $7.4 million in the first nine months of 2007. Interest income was $2.3 million in the first nine months of 2008 and $3.3 million in the first nine months of 2007, respectively. The decrease was primarily due to lower interest rates. Other income in the first nine months of 2007 includes an $8.0 million payment to us for a settlement of litigation against a law firm that formerly represented us in patent litigation, partially offset by a $4.8 million charge for an award against us in our litigation with Alaris Medical Systems.

Income taxes were accrued at an effective tax rate of 32% in the first nine months of 2008 compared to 33% in the first nine months of 2007. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of state income taxes, state credits, tax exempt incomes and deductions for domestic production activities.

Liquidity and Capital Resources

During the first nine months of 2008, our cash, cash equivalents and marketable securities increased by $21.8 million.

Operating Activities: Our cash provided by operating activities tends to increase over time because of our positive operating results. However, it is subject to fluctuations, principally from the impact of integrating new locations from acquisitions, changes in net income, accounts receivable, inventories, payment of trade and other liabilities and the timing of tax payments.

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During the first nine months of 2008, cash provided by operations was $21.3 million. Cash flow from operations for the first nine months of 2008 was mainly comprised of $15.3 million of net income, depreciation and amortization of $10.7 million and net decreases in our operating assets and liabilities of $5.8 million.

Investing Activities: During the first nine months of 2008, cash provided by investing activities was $21.9 million. This was principally comprised of $31.5 million in net investment proceeds, offset by purchases of property and equipment of $9.7 million which were primarily for equipment and mold additions.

We estimate that capital expenditures for all of 2008 will be approximately $14.0 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Cash provided by financing activities in the first nine months of 2008 was $10.7 million from the sale of 677,992 shares of our stock for stock options, including tax benefits, and the employee stock purchase plan.

We have a substantial cash and marketable 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, and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation, as further described in Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Most of our marketable securities are invested in pre-refunded municipal securities. The pre-refunded securities we hold are municipal bonds that are fully collateralized by an escrow account used to pay off the bonds prior to their original maturity dates. The escrow accounts for these securities consist of government Treasury bills. We value these securities by using quotes provided by our brokers and since each instrument is escrowed using government Treasury bills, we do not expect any credit losses.

The auction rate securities we hold are tax exempt debt securities and corporate preferred securities. Auctions of these securities are conducted generally at seven to forty-nine day intervals, depending on the terms of the security, and the securities are bought or sold depending on the interest or dividend rates bid for the securities. Up until February 2008, the auction rate securities market was highly liquid. Beginning in February 2008, a substantial number of auctions failed, meaning that there was not enough demand to sell the entire issue at auction; the immediate effect of a failed auction is that holders cannot sell the securities and the interest or dividend rate on the security generally resets to a penalty rate. If an auction fails, the ability of the holder of the security to liquidate the security would depend on the success of a subsequent auction, whether the issuer raises other financing to redeem the securities, or whether the holder is able to sell the securities to another party; there is no assurance that any of these events will occur. All of our securities are investment grade, and we do not expect any credit losses. We have succeeded in selling a substantial portion of the securities held at December 31, 2007 at par and are attempting to sell more at par, but there is no assurance as to when we will be able to sell additional securities or whether we will be able to sell them without incurring losses.

We are considering investment alternatives for the future. We intend to continue our objectives of avoiding credit and market risk, but there is no assurance that investment yield will be comparable, on an after-tax basis, to the current yields on pre-refunded municipal securities or auction rate securities.

We believe that our existing cash, cash equivalents and marketable 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.

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. We have never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, we do not have any off balance sheet arrangements .

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Contractual Obligations

We have contractual obligations of approximately the amounts set forth in the table below. These amounts exclude purchase orders for goods and services for current delivery. The majority of our purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for goods and services for current delivery, these amounts are excluded from the table below. The commitments under the MCDA are those to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide sales specialists focused on critical care. We believe that our existing cash and marketable securities along with funds expected to be generated from future operations will provide us with sufficient funds to meet commitments under all of our contractual obligations. There are no obligations past 2009. (In thousands)

	2008	2009
MCDA	$ 3,756	$ 5,500
Property and equipment	1,649	
Total	$ 5,405	$ 5,500

Forward Looking Statements

Various portions of this Report, including this Management s Discussion and Analysis, 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, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, and by similar expressions and 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, among other things, statements about:

- future operating results and various elements of operating results, including future expenditures on sales and marketing and product development, future sales and unit volumes of products, future license, royalty and revenue share income, production costs, gross margins, litigation expense, SG&A, R&D expense, future costs of expanding our custom I.V. systems business, income, losses, cash flow, 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, expansion in international markets, selling prices, future increases or decreases in sales of certain products and in certain markets and distribution channels, increases in systems capabilities, introduction and sales of new products, warranty claims, rebates, product returns, bad debt expense, inventory requirements, manufacturing efficiencies and cost savings, unit manufacturing costs; establishment of production facilities outside the U.S., adequacy of production capacity, results of R&D, asset impairment losses, relocation of manufacturing facilities and personnel, effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies, business seasonality and fluctuations in quarterly results, customer ordering patterns and the effects of new accounting pronouncements;

- new or extended contracts with manufacturers and buying organizations, dependence on a small number of customers, effect of the acquisition of Hospira s Salt Lake City manufacturing facility and the manufacture of products for Hospira under the MCDA, cost savings and use of our systems and procedures under the MCDA, and the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices; future purchases of treasury stock; working capital requirements; liquidity and realizable value of our marketable securities, outcome of future auctions of auction rate securities, future investment alternatives, foreign currency denominated financial instruments; capital expenditures; acquisitions of other businesses or product lines; indemnification liabilities; contractual liabilities.

The kinds of statements described above and similar forward looking statements about our future performance are subject to a number of risks and uncertainties which one should consider in evaluating the statements. First, one should consider the factors and risks described in the statements themselves. 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.

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Second, one should read the forward looking statements in conjunction with the Risk Factors in Item 1A of our 2007 Annual Report to the Securities and Exchange Commission (SEC). Also, our actual future operating results are subject to other important factors that we cannot predict or control, including among others the following:

- general economic and business conditions;
- 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;
- 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;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

We disclaim any obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We had a portfolio of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities of $55.8 million as of September 30, 2008. The securities are all investment grade and we believe that we have virtually no exposure to credit risk. As of September 30, 2008, $32.2 million of our marketable securities were invested in pre-refunded municipal securities and $23.6 million of our marketable securities were invested in auction rate securities . The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. For most of the auction rate securities, dividend and interest rates reset at auction at seven to forty-nine day intervals with very little market risk; that is, risk that the fair value of the security will change because of changes in market interest rates. As of September 30, 2008, we had temporary declines of $0.3 million in the market values of the auction rate securities.

Up until early February 2008, the market for our securities was highly liquid. Liquidity has been substantially impaired since then. See Part I, Item 1A. Risk Factors in our 2007 Annual Report to the SEC - *We could be adversely affected by turbulence in the credit markets* and Part I, Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources - *Financing Activities*. We intend to continue our objectives of avoiding credit and market risk in the future.

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 federal-tax-exempt securities and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the euro and Mexican peso. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable and accruals in the same foreign currency, except for Italy, where our net euro asset position at September 30, 2008 was approximately 6.2 million. We expect that in the future, with the growth of our European distribution operation, that net euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin, a petroleum-based raw material. We manage our exposure to changes in those prices through our procurement and supply chain management practices and have experienced price increases on our raw material. We estimate the price increases are approximating $2.0 million annually. We are not dependent upon any single source for any of our principal raw materials and all such materials and products are readily available.

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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, 2008 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 have not been required to pay any penalty to the IRS for failing to make disclosures required with respect to certain transactions that have been identified by the IRS as abusive or that have a significant tax avoidance purpose.

In an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. in the United States District Court for the Central District of California, we alleged that Alaris infringes ICU s patent through the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. On August 2, 2004, the Court denied our request for a preliminary injunction. On December 27, 2004, we amended our complaint to allege that Alaris infringes three additional patents. On July 17, 2006, the Court issued an order interpreting certain claims in the asserted patents in a manner that, if upheld, could significantly impair our ability to enforce those patents against Alaris and potentially others. The Court also issued partial summary judgment in favor of Alaris based on one of those interpretations. On January 22, 2007, the Court granted Alaris summary judgment motion of invalidity as to the remaining claims asserted against Alaris and on February 22, 2007, the Court entered judgment dismissing those remaining claims. The Court s order adjudicated only the asserted claims of the patents in suit, not other claims in the patents. Following entry of the judgment dismissing our case, the Court heard Alaris motion to recover its fees, costs and expenses, and on April 16, 2007, the Court granted in part Alaris motion. On June 28, 2007, the Court awarded Alaris $4.8 million in fees and costs, which were later increased to $5.0 million, plus post-judgment interest accrued monthly. We have appealed the Court s decisions, and oral argument has been scheduled. Because the award of fees and costs is a judgment against us and the outcome of the appeal is uncertain, we recorded a charge of $4.8 million in our financial statements for the quarter ended September 30, 2007. We have not paid the judgment, pending outcome of the appeal.

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc. filed in the United States District Court for the Central District of California, Medegen alleged that ICU Medical infringed one of its patents by offering for sale and selling the CLC2000 and TEGO. Medegen sought monetary damages and injunctive relief. In March 2007, Medegen withdrew its action as to the TEGO. On June 21, 2007, the Court

issued an order interpreting certain terms and phrases of Medegen s patent in a manner that we believe supported our position. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and entered judgment of non-infringement, dismissing Medegen s case with prejudice, on October 19, 2007. On October 19, 2007, the Court also dismissed, without prejudice, our counterclaims that the asserted patent is invalid and unenforceable due to inequitable conduct by Medegen before the United States Patent and Trademark Office. Medegen has appealed the Court s claim construction and summary judgment orders. Oral argument was heard on September 4, 2008, and we are awaiting the decision of the Court of Appeal. We intend to defend ourselves against Medegen s claims in this action.

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. (RyMed), in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of ICU s patents through the manufacture and sale of certain products, including its InVision-Plus valves. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. RyMed has denied our allegations and sued us in the United States District Court for the Central District of California seeking a declaratory judgment of non-infringement and invalidity of our patents and alleging that we have infringed RyMed s trademark and engaged in unfair competition and other improper conduct. RyMed seeks monetary damages and injunctive relief. The District Court has transferred the patent claims to Delaware. The trademark and unfair competition claims remain pending in the Central District of California. ICU will continue to defend itself in the California action, and vigorously pursue its patent infringement claims against RyMed in the Delaware action.

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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 to the SEC for the year ended December 31, 2007, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC. Except for the risk factor set forth below, there have been no material changes in the risk factors as previously disclosed under Risk Factors in Part I, Item 1A of our Annual Report to the SEC for the year ended December 31, 2007.

Our operating results may be adversely affected by unfavorable economic conditions.

Economic conditions worldwide could affect our customers ability to obtain loans for working capital and our customers may not be able to pay us. Although our cash position may mitigate this risk, if global economic conditions, or economic conditions in the United States, remain uncertain or deteriorate further, we may experience material adverse impacts on our business, financial condition and results of operation.

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

Inapplicable

Item 3. Default Upon Senior Securities

Inapplicable

Item 4. Submission of Matters to a Vote of Security Holders

Inapplicable

Item 5. Other Information

None

Item 6. Exhibits

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 100.INS	XBRL Instance Document
Exhibit 100.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 100.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 100.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 100.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
Scott E. Lamb
Chief Financial Officer
(Principal Financial Officer)

Date: October 23, 2008