ICU MEDICAL INC/DE Form 10-Q July 24, 2009 Table of Contents

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended: June 30, 2009

or

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

to

For the transition period from:

Commission File No.: 0-19974

# ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

**951 Calle Amanecer, San Clemente, California** (Address of principal executive offices)

**33-0022692** (I.R.S. Employer Identification No.)

> **92673** (Zip Code)

(949) 366-2183

(Registrant s telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large accelerated filer O

(Do not check if a smaller reporting company)

Non-accelerated filer O

Accelerated filer X

Smaller reporting company O

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

Class Common **Outstanding at July 10, 2009** 14,781,344

ICU Medical, Inc.

Index

Part I - Financial Information	Page Number
Item 1. Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets, at June 30, 2009 and December 31, 2008	3
Condensed Consolidated Statements of Income for the three and six months ended June 30, 2009 and 2008	4
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2009 and 2008	5
Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2009 and 2008	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3. Quantitative and Qualitative Disclosures About Market Risk	20
Item 4. Controls and Procedures	21
Part II - Other Information	
Item 1. Legal Proceedings	21
Item 1A. Risk Factors	21
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3. Default Upon Senior Securities	23
Item 4. Submission of Matters to a Vote of Security Holders	23
Item 5. Other Information	23
Item 6.Exhibits	23
Signature	24

### ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

		June 30, 2009 (unaudited)		December 31, 2008 (1)
ASSETS		(		(-)
CURRENT ASSETS:				
Cash and cash equivalents	\$	62,586	\$	55,696
Investment securities		82,067		56,093
Cash, cash equivalents and investment securities		144,653		111,789
Accounts receivable, net of allowance for doubtful accounts of \$235 at June 30, 2009				
and \$320 at December 31, 2008		27,498		38,423
Inventories		24,752		17,930
Prepaid income taxes		428		4,544
Prepaid expenses and other current assets		5,566		3,471
Deferred income taxes current portion		3,281		3,231
Total current assets		206,178		179,388
PROPERTY AND EQUIPMENT, net		70,482		69,897
PROPERTY HELD FOR SALE		940		940
RESTRICTED CASH		57		6,014
INVESTMENT SECURITIES non-current portion				11,350
GOODWILL		1,478		
INTANGIBLE ASSETS, net		14,868		10,780
DEFERRED INCOME TAXES non-current portion		3,855		3,855
INCOME TAXES RECEIVABLE non-current portion		1,210		1,210
	\$	299,068	\$	283,434
LIABILITIES AND STOCKHOLDERS EQUITY				
CURRENT LIABILITIES:	¢	0.570	¢	7.070
Accounts payable	\$	9,570	\$	7,879
Accrued liabilities		11,243		14,081
Total current liabilities		20,813		21,960
COMMITMENTS AND CONTINGENCIES				
DEFERRED INCOME TAXES non-current portion		5,383		4,007
INCOME TAXES PAYABLE non-current portion		4,436		4,436
STOCKHOLDERS EQUITY:				
Convertible preferred stock, \$1.00 par value Authorized 500 shares; issued and outstanding				
none				
Common stock, \$0.10 par value Authorized 80,000 shares; Issued 14,784 shares at June 30, 2000 and December 21, 2008, article 14,781 shares at June 20, 2000 and 14,721 shares				
2009 and December 31, 2008, outstanding 14,781 shares at June 30, 2009 and 14,731 shares		1 470		1 470
at December 31, 2008		1,478		1,478
Additional paid-in capital		52,040		50,970
Treasury stock, at cost - 2 and 53 shares at June 30, 2009 and December 31, 2008		(85)		(1,623)
Retained earnings		214,107		201,304
Accumulated other comprehensive income		896		902
Total stockholders equity	\$	268,436	\$	253,031 283 434
	J.	299,068	J.	283,434

\$

299,068 \$

283,434

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

<sup>(1)</sup> December 31, 2008 balances were derived from audited consolidated financial statements.

### ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Income

(Amounts in thousands, except per share data)

### (unaudited)

	Three months of 2009	Three months ended June 30,20092008			nded Ju	d June 30, 2008	
REVENUES:							
Net sales	\$ 53,282	\$	48,382 \$	107,477	\$	92,053	
Other	117		210	257		1,193	
TOTAL REVENUE	53,399		48,592	107,734		93,246	
COST OF GOODS SOLD	27,610		27,788	55,379		54,671	
Gross profit	25,789		20,804	52,355		38,575	
OPERATING EXPENSES:							
Selling, general and administrative	16,503		13,685	31,615		26,793	
Research and development	617		1,452	1,355		3,471	
Total operating expenses, net	17,120		15,137	32,970		30,264	
Income from operations	8,669		5,667	19,385		8,311	
OTHER INCOME	305		1,139	623		2,695	
Income before income taxes	8,974		6,806	20,008		11,006	
PROVISION FOR INCOME TAXES	(3,233)		(2,034)	(7,205)		(3,336)	
NET INCOME	\$ 5,741	\$	4,772 \$	12,803	\$	7,670	
NET INCOME PER SHARE							
Basic	\$ 0.39	\$	0.34 \$	0.87	\$	0.55	
Diluted	\$ 0.38	\$	0.33 \$	0.85	\$	0.53	
WEIGHTED AVERAGE NUMBER OF SHARES							
Basic	14,780		13,966	14,758		13,859	
Diluted	15,071		14,381	14,975		14,388	

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

### ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(unaudited)

		Six months en	ded Jun	/
CASH FLOWS FROM OPERATING ACTIVITIES:		2009		2008
	¢	12 802	¢	7 670
Net income	\$	12,803	\$	7,670
Adjustments to reconcile net income to net cash provided by operating activities:		7 227		7.029
Depreciation and amortization Provision for doubtful accounts		7,337		7,028
		(84)		(282)
Stock compensation		1,242		882
Loss on disposal of property and equipment		20		
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired				(2.000)
Accounts receivable		11,182		(2,890)
Inventories		(4,668)		(969)
Prepaid expenses and other assets		(2,635)		565
Accounts payable		1,547		(1,252)
Accrued liabilities		(3,789)		1,037
Prepaid and deferred income taxes		3,682		(813)
Net cash provided by operating activities		26,637		10,976
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property and equipment		(6,852)		(7,122)
Business acquisition, net of cash acquired		(5,663)		(7,122)
Change in restricted cash		5,958		
Proceeds from finance loan repayments		5,750		48
Purchases of investment securities		(55,047)		(12,357)
Proceeds from sale of investment securities		40.423		70,685
Net cash provided (used) by investing activities		(21,181)		51,254
Net cash provided (used) by investing activities		(21,101)		51,234
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of stock options		1,255		4,602
Proceeds from employee stock purchase plan		623		744
Tax benefits from exercise of stock options		48		3,849
Purchase of treasury stock		(560)		
Net cash provided by financing activities		1,366		9,195
Effect of exchange rate changes on cash		68		309
NET INCREASE IN CASH AND CASH EQUIVALENTS		6,890		71,734
CASH AND CASH EQUIVALENTS, beginning of period		55,696		7,873
CASH AND CASH EQUIVALENTS, end of period	\$	62,586	\$	79,607

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

### ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

(Amounts in thousands)

(unaudited)

	Three months of 2009	ended J	une 30, 2008	Six months er 2009	nded Ju	ne 30, 2008
Net income	\$ 5,741	\$	4,772 \$	12,803	\$	7,670
Other comprehensive income (loss), net of tax: Unrealized gain (loss) on investments			347			(288)
Foreign currency translation adjustment	881		(214)	(6)		522
Comprehensive income	\$ 6,622	\$	4,905 \$	12,797	\$	7,904

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

### ICU Medical, Inc.

#### Notes to Condensed Consolidated Financial Statements

June 30, 2009

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

(unaudited)

#### Note 1: Basis of Presentation:

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and reflect all adjustments, consisting of only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated results for the interim periods presented. Results for the interim period are not necessarily indicative of results for the full year. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008.

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 April 2009, the Financial Accounting Standards Board (FASB) issued FSP SFAS 141(R)-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, to amend the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS 141(R). Under the new guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value cannot be determined, companies should typically account for the acquired contingencies using existing guidance. The Company adopted FAS 141(R) and FSP SFAS 141(R)-1 on January 1, 2009. The adoption did not have a material effect on the Company s financial position or results of operations.

In April 2009, the FASB issued FSP SFAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly which provides additional guidance for estimating fair value in accordance with FASB Statement No. 157, Fair Value Measurements , when the volume and level of activity for the asset or liability have significantly decreased. This FSP also includes guidance on identifying circumstances that indicate a transaction is not orderly. The Company

adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on the Company s financial position or results of operations.

In April 2009, the FASB issued FSP SFAS 115-2 and SFAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, to amend the other-than-temporary impairment guidance in debt securities to be based on intent and not more likely than not that the Company would be required to sell the security before recovery and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. The Company adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on the Company s financial position or results of operations.

In May 2009, the FASB issued SFAS 165, Subsequent Events , to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The Company adopted this pronouncement for the quarter ended June 30, 2009. The adoption did not have an effect on the Company s financial position or results of operations.

#### Note 3: Restricted Cash / Intangible Assets

In February 2009, the Company acquired a small manufacturing and distribution company based in Germany for approximately \$5.7 million, which was reflected as restricted cash of \$6.0 million at December 31, 2008. The Company recorded \$5.7 million in intangible assets, which includes \$3.8 million for customer contracts, \$0.4 million for trademarks, \$1.5 million of goodwill and a deferred tax liability of \$1.4 million, due to the non-tax deductibility of the intangible assets.

### Note 4: Fair Value Measurement:

The Company s investment securities, which are considered available for sale and trading consist principally of corporate preferred stocks, certificates of deposit and federal-tax-exempt state and municipal government debt. The Company has \$2.3 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has \$77.4 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities and have observable inputs. The Company has \$2.4 million invested in auction rate 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 quotes received from our brokers which was derived from their internal models combined with internally developed discount factors. In determining a discount factor for each auction rate security, the model weights various factors, including assessments of credit quality, duration, insurance wraps, discount rates, overall capital market liquidity and comparable securities, if any. They are carried at fair value.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of June 30, 2009:

			Que	e measurements : oted prices 1 active		), 2009 using gnificant		
	v	Total carrying value at June 30, 2009		rkets for lentical (Level 1)	ol	other oservable its (Level 2)	un	ignificant observable uts (Level 3)
Available for sale					-		-	
securities	\$	79,642	\$	2,274	\$	77,368	\$	
Trading securities		2,425						2,425
	\$	82,067	\$	2,274	\$	77,368	\$	2,425

The following tables summarize the change in the fair values for Level 3 items for the quarter ended June 30, 2009:

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

	 months ended ne 30, 2009	Six months ended June 30, 2009
Beginning balance	\$ 12,100 \$	15,925
Transfer into Level 3		
Sales	(9,675)	(13,500)
Unrealized holding gain, included in other comprehensive		
income		
Ending balance	\$ 2,425 \$	2,425

The Company has agreements in place with Morgan Stanley & Co. (Morgan) and UBS AG (UBS) that permit the Company to require Morgan and UBS to purchase the Company s auction rate securities at par value plus accrued interest. As of June 30, 2009, the Company has \$2.4 million in auction rate securities. There was less than \$0.1 million increase in the market values of the Company s auction rate securities in the quarter ended June 30, 2009.

### Note 5: Inventories:

Inventories consisted of the following:

	June 30, 2009	December 31, 2008
Raw material	\$ 17,259	\$ 12,531
Work in process	2,723	2,577
Finished goods	4,770	2,822
Total	\$ 24,752	\$ 17,930

#### Note 6: Property and Equipment:

Property and equipment consisted of the following:

	June 30, 2009	December 31, 2008
Machinery and equipment	\$ 51,369	\$ 50,337
Land, building and building improvements	48,877	48,715
Molds	18,820	16,791
Computer equipment and software	11,901	9,890
Furniture and fixtures	1,889	1,983
Construction in progress	4,268	3,479
Total property and equipment, cost	137,124	131,195
Accumulated depreciation	(66,642)	(61,298)
Net property and equipment	\$ 70,482	\$ 69,897

### Note 7: Net Income Per Share:

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of the average market value for the period), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 267,000 and 1,815,000 for the three months ended June 30, 2009 and 2008, respectively and 679,000 and 1,604,000 for the six months ended June 30, 2009 and 2008, respectively.

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

	Three months ended June 30, 2009 2008			Six months er 2009	June 30, 2008		
Net income	\$	5,741	\$	4,772	\$ 12,803	\$	7,670
Weighted average number of common shares outstanding							
(for basic calculation)		14,780		13,966	14,758		13,859
Dilutive securities		291		415	217		529
Weighted average common and common equivalent shares							
outstanding (for diluted calculation)		15,071		14,381	14,975		14,388
EPS basic	\$	0.39	\$	0.34	\$ 0.87	\$	0.55
EPS diluted	\$	0.38	\$	0.33	\$ 0.85	\$	0.53

Income taxes were accrued at an estimated annual effective tax rate of 36.0% in the first half of 2009 compared to 30.3% in the first half of 2008. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities.

#### Note 9: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 63% and 67% of total revenue for the three months ended June 30, 2009 and 2008, respectively and 67% and 66% for the six months ended June 30, 2009 and 2008, respectively. As of June 30, 2009 and December 31, 2008, the Company had accounts receivable from Hospira of 59% and 66%, of consolidated accounts receivable, respectively.

#### Note 10: Commitments and Contingencies:

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 On October 19, 2007, entered judgment of non-infringement, dismissing Medegen s case with prejudice. 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. By decision issued in November 2008, the Federal Circuit reversed the order granting summary judgment and remanded the case to the District Court. The Company intends to defend itself against Medegen s claims in this action. The outcome of this action is uncertain, therefore no accrual has been recorded.

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

In the normal course of business, the Company has agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company s products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, the Company has never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, the Company does not have any off balance sheet arrangements .

Pursuant to the Asset Purchase Agreement with Hospira, the Company has agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of the Company s representations and breaches of the Company s warranties; (ii) defaults of our covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira s rights to indemnification will terminate eighteen months after the closing of the transaction, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided. Notwithstanding the foregoing, the Company is not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify the Company or the Company s affiliates under the MCDA. Although the Company can provide no assurances, the Company does not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

#### Note 11: Subsequent Event:

The Company has evaluated subsequent events through July 22, 2009, which is the date the financial statements were available to be issued.

On July 8, 2009, the Company signed a definitive asset purchase agreement with Hospira to purchase the commercial rights and physical assets of Hospira's critical care product line, which are primarily inventory. The purchase price is estimated at \$35.0 million. The final purchase price will be adjusted to reflect the final net book value of the assets included in the asset purchase agreement. The transaction is subject to customary

closing conditions. While the Company can provide no assurances, the Company expects the transaction to close in the third quarter of 2009.

#### 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 diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom infusion sets and we incorporate our proprietary products into many of those custom infusion sets. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

#### **Critical Accounting Policies**

In our Annual Report on Form 10-K for the year ended December 31, 2008, 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 April 2009, the FASB issued FSP SFAS 141(R)-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies , to amend the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS 141(R). Under the new guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value cannot be determined, companies should typically account for the acquired contingencies using existing guidance. We adopted FAS 141(R) and FSP SFAS 141(R)-1 on January 1, 2009. The adoption did not have a material effect on our financial position or results of operations.

In April 2009, the FASB issued FSP SFAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly which provides additional guidance for estimating fair value in accordance with FASB Statement No. 157, Fair Value Measurements , when the volume and level of activity for the asset or liability have significantly decreased. This FSP also includes guidance on identifying circumstances that indicate a transaction is not orderly. We adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on our financial position or results of operations.

In April 2009, the FASB issued FSP SFAS 115-2 and SFAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, to amend the other-than-temporary impairment guidance in debt securities to be based on intent and not more likely than not that the Company would be required to sell the security before recovery and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. We adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on our financial position or results of operations.

In May 2009, the FASB issued SFAS 165, Subsequent Events , to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. We adopted this pronouncement for our quarter ended June 30, 2009. The adoption did not have an effect on our financial position or results of operations.

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 infusion sets, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices beyond the CLAVE.

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 Hospira Agreements, we manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. In 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into an agreement with Hospira to produce their critical care products, including invasive monitoring, angiography products and certain other products they had manufactured at that facility. In July 2009, we entered into a definitive asset purchase agreement to acquire the commercial rights and physical assets from Hospira s critical care product line, which, when the transaction closes, will provide us with the ability to control all aspects of our critical care product line. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. We are expanding our custom products business through increased sales to medical product manufacturers, independent distributors and direct sales to the end users of our product. These expansions include our 2008 agreement with Premier and an agreement extension with MedAssets. Both organizations are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately \$37.0 million or 34% of total revenue in 2008. We expect continued increases in sales of custom

#### Table of Contents

infusion sets and custom oncology products. As part of this effort, we have recently introduced a number of new products: the TEGO for use in dialyses, the Orbit 90 diabetes set, and a line of oncology products including the Spiros male luer connector device, the Genie vial access device, custom I.V sets and ancillary products specifically designed for chemotherapy. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

Custom products and new products will be of increasing importance to us in future years. We expect continued growth in 2009 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., to date, 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.

In 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment and entered into the Manufacturing Commercialization Development Agreement (MCDA) under which we produced for sale, exclusively to Hospira, substantially all the products, primarily critical care, that Hospira had manufactured at that facility. Under this agreement, Hospira retained commercial responsibility for the products we produced, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The U.S. market for most of the critical care products that we sell to Hospira has been declining in recent years. Under the MCDA, we manufactured the products and Hospira was responsible for sales to end customers, and we had little ability to directly influence Hospira's sales and marketing efforts, and our sales under the MCDA were subject to fluctuations over which we had little control. On July 8, 2009, we signed a definitive purchase agreement with Hospira to acquire the commercial rights and physical assets of their critical care product line, which are primarily inventory. This purchase will provide us with complete control over worldwide commercial responsibility for the MCDA, we were also committed to fund certain critical care research and to provide sales specialist support. Both obligations under the MCDA will cease upon the closing of the asset purchase transaction with Hospira. While we can provide no assurances, we anticipate closing this asset purchase in the third quarter of 2009.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In the first half of 2009 and years ended 2008, 2007 and 2006, our revenues from worldwide sales to Hospira were 67%, 69%, 73% and 77%, respectively, of total revenues. Although we can provide no assurances, we expect this percentage will decrease once we complete the purchase of Hospira s critical care product line. 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.

In February 2009, we acquired a small manufacturing and distribution company based in Germany for \$5.7 million. The products and distribution from this company are in the oncology and neonatal 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, when compared to the larger market of standard products, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity in this market. Product development or acquisition efforts may not succeed, and even if we do develop or acquire products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira s position in the market, could have an adverse effect on us. Increased expenditures for sales and

marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

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

	Three months ended		Six months	ended		
	June 3	0,	June 3	0,	Fiscal Year	Ended
Product Line	2009	2008	2009	2008	2008	2007
CLAVE	40%	38%	39%	39%	39%	38%
Custom products	34%	35%	34%	34%	34%	31%
Critical care	16%	18%	17%	18%	18%	23%
Other products	10%	9%	10%	8%	8%	7%
License, royalty and revenue						
share	0%	0%	0%	1%	1%	1%
Total	100%	100%	100%	100%	100%	100%

### Table of Contents

We sell our I.V. administration products to independent distributors, 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 infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. Under the MCDA, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. Upon completing the purchase of Hospira s critical care product line, which is expected to occur in the third quarter of 2009, we will sell invasive monitoring and angiography to independent distributors and through direct sales. We also sell certain other products to a number of other medical product manufacturers.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer s products could have a material adverse effect on our operating results.

We have an ongoing 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 will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and in our Salt Lake City facility in 2008. These efforts are ongoing in both facilities and will continue in the second half of 2009. In July 2009, we purchased land in Slovakia. We have plans to build an assembly plant in Slovakia that will serve our European product distribution. We expect this plant to be operational in the second half of 2010. We may establish additional production facilities outside the U.S.

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

	Three months ended June 30,		Six months June 3		Fiscal Year Ended		
Channel	2009	2008	2009	2008	2008	2007	
Medical product manufacturers	61%	66%	64%	67%	67%	71%	
Domestic distributors/direct	20%	19%	17%	18%	18%	16%	
International customers	19%	15%	19%	15%	15%	13%	
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.

*Quarter-to-quarter and six month-to-six month comparisons:* We present summarized income statement data in Item 1- Financial Statements. The following table shows, for the year ended December 31, 2008 and the three and six months ended June 30, 2009 and 2008, the percentages of each income statement caption in relation to total revenues.

	Fiscal Year	Three months June 30,		Six months o June 30	
	2008	2009	2008	2009	2008
Revenue					
Net sales	99%	100%	100%	100%	99%
Other	1%	%	%	%	1%
Total revenues	100%	100%	100%	100%	100%
Gross profit	44%	48%	43%	49%	41%
•					
Selling, general and administrative expenses	26%	31%	28%	30%	29%
Research and development expenses	2%	1%	3%	1%	3%
Total operating expenses	28%	32%	31%	31%	32%
Income from operations	16%	16%	12%	18%	9%
Other income	2%	1%	2%	1%	3%
Income before income taxes	18%	17%	14%	19%	12%
Income taxes	6%	6%	4%	7%	4%
Net income	12%	11%	10%	12%	8%

**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. The current challenging economic environment has not had a meaningful impact on our business in the operating results reported in this report, however, towards the end of the first quarter of 2009, some of our customers stated their intent to take a more conservative stance on inventory levels. Through the end of the second quarter of 2009, this has not caused a significant impact to our earnings. Our expenses often do not fluctuate consistently with net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

### Quarter Ended June 30, 2009 Compared to the Quarter Ended June 30, 2008

Revenues were \$53.4 million in the second quarter of 2009, compared to \$48.6 million in the second quarter of 2008.

*Distribution channels:* Net U.S. sales to Hospira in the second quarter of 2009 were \$31.8 million, compared to net sales of \$30.9 million in the second quarter of 2008. The \$0.9 million increase was primarily from a \$2.5 million increase in CLAVE sales, offset by a \$0.7 million decrease in critical care product sales and a \$0.5 million decrease custom product sales. The increase in CLAVE sales was from higher unit sales due to increased market share through Hospira. The decrease in critical care product sales was due to lower unit sales for certain critical care products. The decrease in custom products was primarily due to lower unit sales in custom oncology products, partially offset by higher unit sales in custom infusion sets from the conversion by certain of our customers from a competitor s standard sets to our custom systems. Excluding critical care products, we expect minimal growth in sales to Hospira in 2009 as Hospira take a more conservative stance in their inventory levels. As a result of our July 8, 2009 definitive asset purchase agreement with Hospira for their critical care product line, we will defer revenue recognition on all critical care sales made to Hospira from July 8, 2009 until the transaction is closed. Revenue on these shipments will be recognized when the inventory is sold to the end customer. After the transaction is closed, we expect our critical care sales will be made to independent distributors and through direct sales, domestically and internationally. There is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in the second quarter of 2009 (including Canada) were \$10.7 million compared to \$9.3 million in the second quarter of 2008, an increase of 15%. The increase was primarily from increased oncology and TEGO sales, both newer product lines and increased custom product sales. The increase in custom product sales was primarily in increased unit volume sales in custom infusion sets. We continue to expect increases in domestic distributor sales in 2009 compared to 2008, principally from growth in custom products and new product sales, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were \$9.9 million in the second quarter of 2009, compared with \$7.3 million in the second quarter of 2008. The increased sales were primarily from new product sales of \$2.2 million and increased CLAVE sales of \$0.3 million. We acquired a small company in Germany in the middle of the first quarter of 2009. Sales from this acquisition were approximately \$1.2 million in the second quarter of 2009. Our international growth in other new product sales includes custom and non-custom oncology products, TEGO used in dialysis and Orbit 90 diabetes sets. The CLAVE increase is from

#### Table of Contents

increased unit volume due to increased market share and demographic growth. The majority of the increase was attributable to increased sales in Europe. We expect increases in international customer sales in 2009, primarily from increased custom product sales and oncology product sales and additional sales of our new products from our recent acquisition, although there is no assurance that these expectations will be realized.

*Product and other revenue:* Net sales of CLAVE products increased from \$18.4 million in the second quarter of 2008 to \$21.3 million in the second quarter of 2009, an increase of \$2.9 million or 16%. This increase was primarily from increased sales to Hospira from increased market share and demographic growth. We continue to expect increases in CLAVE product sales in 2009 compared to 2008, although there is no assurance that these expectations will be realized.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were \$18.1 million in the second quarter of 2009 compared to \$17.0 million in the second quarter of 2008. This increase was primarily comprised of increased sales of custom infusion sets of \$1.5 million, partially offset by lower custom critical care sales of \$0.5 million. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The lower custom critical care sales are due to lower unit volumes. We expect increases in custom infusion set sales and new custom oncology sales in 2009 compared to 2008. We expect lower custom critical care sales in 2009 compared to 2008 because of lower unit sales in the first half of 2009 compared to the first half of 2008 and because of the deferral of revenue on critical care sales to Hospira from July 8, 2009 until the closing of the asset purchase of Hospira 's critical care product line. Revenue on these shipments will be recognized when the inventory is sold to the end customer after we close the asset purchase.

Critical care product sales were \$8.3 million in the second quarter of 2009 compared to \$9.0 million in the second quarter of 2008. This decrease was due to lower unit sales of certain critical care products. We expect lower critical care sales in 2009 compared to 2008 because of the deferral of revenue on critical care sales to Hospira from July 8, 2009 until the closing of the purchase of Hospira's critical care product line and expected lower unit volumes. Revenue on these shipments will be recognized when the inventory is sold to the end customer after we close the asset purchase.

Since we will defer all custom and non-custom critical care sales to Hospira from July 8, 2009 until the closing of the asset purchase with Hospira, we expect the greatest impact in lower revenue from critical care sales to occur in the third quarter of 2009. Revenue on these shipments will be recognized when the inventory is sold to the end customer after we close the asset purchase. The asset purchase is expected to close in the third quarter of 2009. Upon the closing of the asset purchase, we will be responsible for all aspects of the critical care line, including sales, marketing, customer contracting and distribution and we expect that we will begin distribution of critical care products directly to existing customers. We anticipate entering into a transition services agreement with Hospira to facilitate the transition. We can provide no assurances, however, that we will be successful in maintaining relationships with major buying organizations fostered by Hospira or that customers will purchase products from us, with the same or similar terms. Any failure on our part to adequately market and sell the critical care line will have an adverse effect on our financial results. Our total custom and non-custom critical care sales in the second quarter of 2009 were \$10.0 million and in the third quarter of 2008 were \$13.7 million. We can provide no assurance that the asset purchase will not be delayed or that the asset purchase will close at all.

Our new oncology product sales, including custom oncology, were \$3.1 million in the second quarter of 2009 compared to \$2.4 million in the second quarter of 2008.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.1 million in the second quarter of 2009 and \$0.2 million in the second quarter of 2008. 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 margins* for the second quarters of 2009 and 2008 were 48% and 43%, respectively. Favorable exchange rates and lower transportation costs contributed two percent and one percent, respectively, to the five percent increase in our gross margin. The balance of the margin change was from favorable product mix and improved manufacturing efficiencies at our Mexico facility.

We estimate our gross margin in 2009 will approximate 46-47%. There is no assurance that these expectations will be realized.

*Selling, general and administrative expenses* (SG&A) were \$16.5 million and 31% of revenues in the second quarter of 2009, compared with \$13.7 million and 28% of revenues in the second quarter of 2008. The increase was primarily from increased legal expenses of \$1.4 million and increased compensation and benefits of \$0.8 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from 14 new hires in sales, which include the addition of personnel from our acquisition in Germany, and higher salary costs. We expect SG&A in 2009 to be approximately 29-30% of revenue with the increase principally from the addition of sales personnel, increased travel related expenses, increased compensation and stock compensation expense and higher legal expenses from ongoing litigation. There is no assurance that these expectations will be realized.

### Table of Contents

**Research and development expenses** (**R&D**) were \$0.6 million and one percent of revenue in the second quarter of 2009 compared to \$1.5 million and three percent of revenue in the second quarter of 2008. The decrease is primarily due to our increased focus on our core projects that started in the latter half of 2008 and MedScanSonics ceasing operations in 2008. We expect R&D in 2009 to be one to two percent of revenue, although there is no assurance that these expectations will be realized.

*Other income* decreased \$0.8 million to \$0.3 million in the second quarter of 2009 compared to \$1.1 million in the second quarter of 2008. Other income in the second quarter of 2009 is primarily comprised of interest income. Other income in the second quarter of 2008 includes \$0.7 million of interest income and \$0.4 million from a payment under a settlement agreement. The decrease in interest income was due to lower interest rates.

*Income taxes* were accrued at an estimated annual effective tax rate of 36% in the second quarter of 2009 compared to 30% in the second quarter of 2008. The 2008 rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities. We expect our effective tax rate to be approximately 36% in 2009.

#### Six Months Ended June 30, 2009 Compared to Six Months Ended June 30, 2008

Revenues were \$107.7 million in the first half of 2009, compared to \$93.2 million in the first half of 2008.

*Distribution channels:* Net U.S. sales to Hospira in the first half of 2009 were \$66.6 million, compared to net sales of \$59.7 million in the first half of 2008. The \$6.9 million increase was primarily from a \$5.1 million increase in CLAVE sales, \$1.5 million increase in critical care sales and \$0.6 million increase in custom product sales. The increase in CLAVE sales was primarily from higher unit sales due to increased market share through Hospira. The increase in critical care product sales was due to higher unit sales for certain critical care products. The increase in custom products was comprised of higher unit sales in custom infusion sets from the conversion by certain of our customers from a competitor s standard sets to our custom systems, partially offset by lower unit sales in custom critical care and custom oncology products.

Net sales to domestic distributors/direct in the first half of 2009 (including Canada) were \$18.9 million compared to \$17.0 million in the first half of 2008, an increase of 12%. The increase was primarily from oncology and TEGO sales, both newer product lines and increased custom product sales. The increase in custom product sales was primarily in increased unit volume sales in custom infusion sets.

Net sales to international customers (excluding Canada) were \$20.1 million in the first half of 2009, compared with \$13.5 million in the first half of 2008. The increased sales were primarily from new product sales of \$5.8 million and increased CLAVE sales of \$0.8 million. We acquired a small company in Germany in the middle of the first quarter of 2009. Sales from this acquisition were approximately \$1.9 million in the first half of 2009. Our international growth in other new product sales includes custom and non-custom oncology products, TEGO used in dialysis and Orbit 90 diabetes sets. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The majority of the increase was attributable to increased sales in Europe.

*Product and other revenue:* Net sales of CLAVE products increased from \$36.7 million in the first half of 2008 to \$42.5 million in the first half of 2009, an increase of \$5.8 million or 16%. This increase was primarily from increased sales to Hospira from increased market share and demographic growth.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were \$37.0 million in the first half of 2009 compared to \$31.8 million in the first half of 2008. This increase was primarily comprised of increased sales of custom infusion sets and custom oncology products of \$2.9 million and \$2.8 million, respectively, partially offset by lower custom critical care sales of \$0.5 million. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The increased sales in custom oncology was because it is a new product line. The lower custom critical care sales are due to lower unit volumes.

Critical care product sales were \$17.9 million in the first half of 2009 compared to \$16.4 million in the first half of 2008. This increase was due to higher unit sales of certain critical care products.

Our new oncology product sales, including custom oncology, were \$7.4 million in the first half of 2009 compared to \$3.7 million in the first half of 2008.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.3 million in the first half of 2009 and \$1.2 million in the first half of 2008. The decrease from 2008 was due to an exclusivity payment we received in 2008 that did not recur in 2009. 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.

#### Table of Contents

*Gross margins* for the first half of 2009 and 2008 were 49% and 41%, respectively. Favorable exchange rates and lower transportation costs contributed two percent and one percent, respectively, to the eight percent increase in our gross margin. The balance of the margin change was from favorable product mix and improved manufacturing efficiencies at our Mexico facility.

*Selling, general and administrative expenses* (SG&A) were \$31.6 million and 30% of revenues in the first half of 2009, compared with \$26.8 million and 29% of revenues in the first half of 2008. The increase was primarily from increased legal expenses of \$2.8 million and increased compensation and benefits of \$1.2 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from 14 new hires in sales, which include the addition of personnel from our acquisition in Germany, and higher salary costs.

*Research and development expenses* (**R&D**) were \$1.4 million and one percent of revenue in the first half of 2009 compared to \$3.5 million and four percent of revenue in the first half of 2008. The decrease is primarily due to our increased focus on our core projects that started in the latter half of 2008 and MedScanSonics ceasing operations in 2008.

*Other income* decreased \$2.1 million to \$0.6 million in the first half of 2009 compared to \$2.7 million in the first half of 2008. Other income in the first half of 2009 is primarily comprised of interest income. Other income in the first half of 2008 includes \$1.7 million of interest income and \$1.0 million from a payment under a settlement agreement. The decrease in interest income was due to lower interest rates.

*Income taxes* were accrued at an estimated annual effective tax rate of 36% in the first half of 2009 compared to 30% in the first half of 2008. The 2008 rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities.

### Liquidity and Capital Resources

During the first half of 2009, our cash, cash equivalents and investment securities increased by \$21.5 million.

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

During the first half of 2009, our cash provided by operations was \$26.6 million, which was mainly comprised of net income of \$12.8 million, depreciation and amortization of \$7.3 million, stock compensation expense of \$1.2 million, offset by changes in our operating assets and liabilities. The \$11.2 million decrease in accounts receivable and \$4.7 million increase in inventory were the largest contributors to the change in our operating assets and liabilities. The decrease was primarily due to cash collection on sales from the fourth quarter of 2008. The increase in inventory was primarily due to increases in safety stock and additional investments related to our manufacturing process improvement initiative.

*Investing Activities:* During the first half of 2009, cash used by investing activities was \$21.2 million. This was primarily comprised of net investment purchases of \$14.6 million and cash paid for purchases of property and equipment of \$6.9 million which were primarily for equipment and mold additions.

We estimate that our capital expenditures in 2009 will approximate \$17.0 million, including an estimated \$4.0 million to purchase land and begin construction of a manufacturing plant for our custom products in Slovakia. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

In July 2009, we signed a definitive asset purchase agreement with Hospira to acquire the commercial rights and physical assets of Hospira's critical care line. This purchase price is estimated at \$35.0 million which we intend to pay for using cash and cash equivalents. The final purchase price will be adjusted to reflect the final net book value of the assets included in the asset purchase agreement. We anticipate closing this transaction in the third quarter of 2009.

*Financing Activities:* Our cash provided by financing activities was \$1.4 million in the first half of 2009. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$1.9 million from the sale of 67,118 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

#### Table of Contents

In July 2008, we announced a program to purchase up to \$40.0 million of our common stock. We purchased \$5.9 million in 2008 and \$0.6 million in the first quarter of 2009. We did not make any purchases in the second quarter. Additional share repurchases may be made as we deem appropriate and based upon prevailing market and business conditions.

We have a substantial cash and investment security position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, and to take advantage of acquisition opportunities that may arise. Our primary investment goal is principal preservation, as further described below in Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk of this Quarterly Report on Form 10-Q.

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

#### **Off Balance Sheet Arrangements**

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, we do not have any off balance sheet arrangements .

Pursuant to the Asset Purchase Agreement with Hospira, we have agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of our representations and breaches of our warranties; (ii) defaults of our covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira s rights to indemnification will terminate eighteen months after the closing of the transaction, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided. Notwithstanding the foregoing, we are not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under the MCDA. Although we can provide no assurances, we do not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

### **Contractual Obligations**

We have contractual obligations, at June 30, 2009, 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. If the Hospira critical care asset purchase closes as we expect it will, the obligations under the MCDA will terminate. We have excluded from the table below, the FASB Interpretation

No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement no. 109 (FIN 48) noncurrent liability of \$4.4 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the FIN 48 liabilities.

	2009
	(in thousands)
MCDA	\$ 7,568
Property and equipment	3,100
Total	\$ 10,668

#### **Forward Looking Statements**

Various portions of this Quarterly Report on Form 10-Q, 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, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we identify them by using words such as believe, expect,

#### Table of Contents

estimate, plan, will, continue, could, may, and by similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

• future 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 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, planned increases in marketing, 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., plans and timing of the establishment of a plant in Slovakia, adequacy of production capacity, results of R&D, initiatives to improve the ICU Production System, asset impairment losses, relocation of manufacturing facilities and personnel, planned increases in the number of 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; and

• 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, expected timing of the closing and the effects of the purchase of Hospira's critical care product line; 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 investment 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 and contractual liabilities.

Forward-looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, one should read the forward looking statements in conjunction with the Risk Factors discussed in Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008, in Part II, Item 1A of this Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 and our other reports and registration statements filed with the SEC. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

general economic and business conditions, both in the U.S. and internationally;

- outcome of litigation;
- fluctuations in foreign exchange rates;
- increases in labor costs or competition for skilled workers;
- unexpected delays or complications in the closing of the purchase of Hospira s critical care product line;
- 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.

The forward-looking statements contained in this Quarterly Report on Form 10-Q are made only as of the date hereof. We assume no 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, federal-tax exempt state and municipal government debt securities and certificates of deposit of \$82.1 million as of June 30, 2009. The securities are all investment grade. As of June 30, 2009, \$77.4 million of our investment securities were invested in pre-refunded municipal securities, \$2.4 million were invested in auction rate securities and \$2.3 million were certificates of deposit. 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 fourteen to thirty-five day intervals. For the quarter ended June 30, 2009, we had less than \$0.1 million in increases in the market values of the auction rate securities.

Up until early February 2008, the market for our auction rate securities was highly liquid. However, as a result of liquidity issues in the global credit and capital markets, auctions for all of our auction rate securities failed beginning in February 2008 when sell orders exceeded buy orders. The failures of these auctions do not affect the value of the collateral underlying the auction rate securities, and we continue to earn and receive interest on our auction rate securities at pre-determined formula with spreads tied to particular interest rate indexes. Liquidity has been substantially impaired since February 2008 and accordingly we have substantially reduced our position in these types of investments since that time. We have further mitigated liquidity concerns by acquiring put options on our auction rate securities from Morgan Stanley & Co. and UBS AG. The put options are enforceable, non-transferrable rights and agreement to purchase our existing auction rate securities at par value plus accrued interest. We intend to continue our investment objectives of avoiding credit and market risk in the future. During the second quarter of 2009, we reduced our holdings of auction rate securities from \$11.7 million as of March 31, 2009 to \$2.4 million as of June 30, 2009.

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, commercial paper and corporate preferred stocks in our portfolio and market conditions specific to the securities in which we invest. A two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately \$0.5 million to investment income based on the investment securities balance at December 31, 2008.

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. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2008 and our manufacturing spending from 2008 would impact our cost of goods sold by approximately \$1.8 million. 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 our European operations, where our net Euro asset position at June 30, 2009 and 2008 were approximately 11.5 million and 6.1 million, respectively. 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. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to

date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available. Based on our average price for resin in fiscal year 2008, a 10% increase to the price of resin would result in approximately a \$0.6 million change in material cost.

### **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 June 30, 2009 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

As previously reported, in an action filed June 16, 2004 entitled <u>ICU Medical. Inc. v. Alaris Medical Systems, Inc.</u> in the United States District Court for the Central District of California, we alleged that Alaris infringes on several of our patents through the manufacture and sale of its SmartSite and SmartSite Plus Needle-Free Valves and Systems. As previously reported, in a series of decisions, the District Court dismissed our claims, including our request for a preliminary injunction, and awarded Alaris \$5.0 million in fees and costs, plus post-judgment interest. On March 13, 2009, the Federal Circuit affirmed the District Court s decision. We paid the award of attorneys fees, costs and interest in the total sum of \$5.5 million, in the second quarter of 2009.

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

Item 1A. Risk Factors.

In evaluating an investment in our common stock, investors should consider carefully, among other things, the risk factors previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008, 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 on Form 10-K with the SEC for the year ended December 31, 2008.

Unexpected changes in our arrangements with Hospira or unexpected difficulties in connection with the purchase of Hospira s critical care product line may cause a decline in our sales could result in a significant reduction in our sales and profits.

We depend on Hospira for a high percentage of our sales. The table below shows our total revenue and percentage of total revenue attributable to various types of customers for the first six months of 2009 and years ended December 31, 2008 and 2007 (dollars in millions):

	Six months ended		Y	ears Ended I	December 31,	
	June 30, 2009		2008		2007	
Hospira (U.S.)	\$ 66.6	62% \$	132.6	65%	\$ 129.7	69%
Other manufacturers	1.9	2%	3.7	2%	2.7	1%
Domestic distributors/direct sales	18.9	18%	35.9	17%	29.5	16%
International customers	20.0	18%	30.8	15%	23.7	13%
Other revenue	0.3	0%	1.7	1%	2.5	1%

Our principal agreements with Hospira are the MCDA, a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom infusion systems. The MCDA is scheduled to expire in 2025 and the latter two agreements are scheduled to expire in 2014. Upon the closing of our planned asset purchase of Hospira s critical care product line, the commitments under the MCDA 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 will be terminated.

### Table of Contents

The U.S. market for critical care products has been declining in recent years and our sales of critical care products to Hospira declined in 2008 compared to 2007. We expect further declines in 2009. If the market for critical care products continues to decline or if we have significant decreases in our prices to Hospira under the MCDA that are not offset by increased sales volume, our critical care product sales could continue to decline, resulting in a substantial reduction to our sales and profits.

Under the terms of our agreements with Hospira, including the MCDA, we are dependent on the marketing and sales efforts of Hospira for a large percentage of our sales, and Hospira determines the prices at which the products that we sell to Hospira will be sold to its customers. Hospira has conditional exclusive rights to sell CLAVE and our other products as well as custom infusion systems under the SetSource program in many of its major accounts, and exclusive rights to sell products we produce under the MCDA. If Hospira is unable to maintain its position in the marketplace, our sales and operations could be adversely affected.

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in the third and fourth quarters of 2004. If the steps we have taken to monitor and control the amount of Hospira s inventory of CLAVE products to avoid future inventory reductions are not successful we could experience sharp fluctuations in sales of CLAVE products to Hospira in the future.

Our ability to maintain and increase our market penetration depends on the success of our arrangement with Hospira and Hospira s arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells more competing products, whether manufactured by themselves or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

In contrast to our dependence on Hospira, our principal competitors in the market for protective I.V. connection systems are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and alternate site healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales to and dependence on Hospira.

On July 8, 2009, we entered into a definitive asset purchase agreement with Hospira to acquire the commercial and physical assets of Hospira s critical care line, which are primarily inventory. This asset purchase is expected to close in the third quarter of 2009. We can provide no assurance that the asset purchase will not be delayed or that the asset purchase will close at all. Upon the closing of the asset purchase, we will be responsible for all aspects of the critical care line, including sales, marketing, customer contracting and distribution. In connection with the closing of the asset purchase, our rights and obligations under the MCDA will be released. We anticipate entering into a transition services agreement with Hospira to facilitate the transition, but we can provide no assurances that the transition will occur without delays or disruptions. Any delay or disruption in the transition may reduce or eliminate the expected benefits from the transaction.

Upon the closing of the asset purchase, we expect that we will begin distribution of critical care products directly to existing customers. We can provide no assurances, however, that we will be successful in maintaining relationships with major buying organizations fostered by Hospira. Even if we can maintain such relationships, we can provide no assurances that customers will purchase products from us, with the same or similar terms. Furthermore, we can provide no assurances that we will be as successful as Hospira in marketing the critical care product line.

Any failure on our part to adequately market and sell the critical care line will have an adverse effect on our financial results.

Although we expect the transaction, once closed, will reduce the percentage of our revenues attributable to Hospira, we expect that Hospira will continue to be one of our most important customers, particularly with respect to our CLAVE products and custom infusion systems. With respect to these products, we remain dependent on our continued relationship with Hospira as well as Hospira's position in the marketplace. While we do not anticipate changes in our sales to Hospira of these products, we can provide no assurances that our relationship will not change, resulting in adverse effects on sales and operations.

#### Table of Contents

We are increasingly dependent on manufacturing in Mexico and could be adversely affected by any economic, social or political disruptions

We continue to expand our production in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations. In 2008, production costs in Mexico were approximately \$58.2 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all the production in Mexico is exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

As of December 31, 2008, we employed 1,165 people in our plant in Ensenada, Mexico and we expect this number to increase during 2009. Business activity in the Ensenada area has expanded significantly, providing increased employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and result in an increase in labor rates. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

Additionally, recent political and social instability resulting from increased violence in certain areas of Mexico have raised concerns about the safety of our personnel. These concerns may hinder our ability to send domestic personnel abroad and to hire and retain local personnel. Such concerns may require us to increase security for personnel traveling to our Mexico facility or to conduct more operations from the United States rather than Mexico, which may negatively impact our operations and result in higher costs and inefficiencies.

### 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

The following is a description of matters submitted to a vote of our stockholders at our Annual Meeting of Stockholders held on May 15, 2009:

A) Jack W. Brown and Richard H. Sherman, M.D. were elected as directors to hold office until the 2012 Annual Meeting. Votes cast for and withheld with respect to the nominees were as follows:

	Votes For	Votes Withheld
Jack W. Brown	11,758,534	1,144,384
Richard H. Sherman, M.D.	11,016,301	1,886,617

The terms of the following directors were continued after the Annual Meeting: George A. Lopez, M.D., John J. Connors, Michael T. Kovalchik, III, M.D., Joseph R. Saucedo and Robert S. Swinney, M.D.

B) A proposal to ratify the selection of Deloitte & Touche LLP as the independent registered public accounting firm for the Company for the year ending December 31, 2009:

For	Against	Abstain
12,898,735	1,287	2,896

### **Item 5. Other Information**

None

### Item 6. Exhibits

Exhibit 3.1	Registrant s Bylaws, as amended
Exhibit 31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

### Table of Contents

### 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: July 24, 2009

### Exhibit Index

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