

CRITICARE SYSTEMS INC /DE/
Form 10-Q
November 13, 2003

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 September 30, 2003

OR

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

For the transition period from _____ to _____

Commission file number -0-16061

CRITICARE SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware

39-1501563

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

20925 Crossroads Circle, Suite 100, Waukesha, Wisconsin 53186
(Address of principal executive offices) (Zip Code)

Registrant's telephone number including area code (262) 798-8282

N/A

Former name, former address and former fiscal year, if changed since last report.

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 No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Number of shares outstanding of each class of the registrant's classes of common stock as of September 30, 2003:
Class A Common Stock 11,075,269 shares.

CRITICARE SYSTEMS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2003 AND JUNE 30, 2003

(UNAUDITED)

ASSETS	September 30, 2003	June 30, 2003
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,866,322	\$ 3,716,446
Accounts receivable, less allowance for doubtful accounts of \$300,000	5,502,349	5,627,198
Other receivables	454,885	553,147
Inventories	6,277,910	6,347,208
Prepaid expenses	364,817	340,934
Total current assets	16,466,283	16,584,933
Property, plant and equipment net	2,065,034	2,093,408
License rights and patents net	82,236	83,986
TOTAL ASSETS	\$ 18,613,553	\$ 18,762,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,425,979	\$ 2,272,953
Accrued liabilities:		
Compensation and commissions	870,381	850,034
Product warranties	353,729	312,000
Other	282,669	254,470
Total current liabilities	3,932,758	3,689,457
OTHER LONG-TERM OBLIGATIONS	34,654	38,662
TOTAL LIABILITIES	3,967,412	3,728,119
STOCKHOLDERS' EQUITY:		

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Preferred stock - \$.04 par value, 500,000 shares authorized no shares issued or outstanding	---	---
Common stock - \$.04 par value, 15,000,000 shares authorized, 11,204,024 shares issued, and 11,075,269 and 11,073,832 outstanding, respectively	448,161	448,161
Additional paid-in capital	23,361,230	23,360,244
Common stock held in treasury (128,755 and 130,192 shares, respectively)	(416,941)	(419,618)
Subscriptions receivable	(225,000)	(225,000)
Retained earnings (accumulated deficit)	(8,517,827)	(8,126,097)
Cumulative translation adjustment	(3,482)	(3,482)
Total stockholders' equity	14,646,141	15,034,208
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 18,613,553	\$ 18,762,327

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
THREE MONTHS ENDED SEPTEMBER 30, 2003 AND 2002

(UNAUDITED)

	2003	2002
NET SALES	\$ 6,372,417	\$ 6,304,347
COST OF GOODS SOLD	3,798,010	3,907,000
GROSS PROFIT	2,574,407	2,397,347
OPERATING EXPENSES:		
Sales and marketing	1,507,446	1,326,960
Research, development and engineering	600,593	628,940
Administrative	901,258	957,229
Total	3,009,297	2,913,129
LOSS FROM OPERATIONS	(434,890)	(515,782)
OTHER INCOME (EXPENSE):		
Interest expense		(91,533)

Interest income	9,739	15,865
Other income	33,421	299,799
	<u> </u>	<u> </u>
Total	43,160	224,131
LOSS BEFORE INCOME TAXES	(391,730)	(291,651)
INCOME TAX PROVISION		
	<u> </u>	<u> </u>
NET LOSS	\$ (391,730)	\$ (291,651)
	<u> </u>	<u> </u>
NET LOSS PER COMMON SHARE		
Basic and diluted	\$ (0.04)	\$ (0.03)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
Basic and diluted	11,074,738	11,072,682

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
THREE MONTHS ENDED SEPTEMBER 30, 2003 AND 2002

(UNAUDITED)

	2003	2002
	<u> </u>	<u> </u>
OPERATING ACTIVITIES:		
Net loss	\$ (391,730)	\$ (291,651)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	143,178	228,655
Amortization	1,750	1,750
Provision for doubtful accounts	2,352	
Provision for obsolete inventory	95,000	364,000
Gain on sale of Immtech stock		(241,746)
Gain on sale of building		(41,208)
Changes in assets and liabilities:		
Accounts receivable	122,497	544,245
Other receivables	98,262	(84,914)
Inventories	(43,842)	(568,513)
Prepaid expenses	(23,883)	(2,135)
Accounts payable	153,026	94,687

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Accrued liabilities	86,267	117,731
Net cash provided by operating activities	242,877	120,901
INVESTING ACTIVITIES:		
Purchases of property, plant and equipment, net	(96,664)	(306,073)
Proceeds from sale of Immtech stock		241,746
Proceeds from sale of building		3,795,164
Net cash (used in) provided by investing activities	(96,664)	3,730,837
FINANCING ACTIVITIES:		
Retirement of long-term debt		(3,197,125)
Repurchase of Company common stock		(121,359)
Proceeds from issuance of common stock	3,663	9,986
Net cash provided by (used in) financing activities	3,663	(3,308,498)
EFFECT OF EXCHANGE RATE CHANGES ON CASH		268
NET INCREASE IN CASH AND CASH EQUIVALENTS	149,876	543,508
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,716,446	3,523,070
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 3,866,322	\$ 4,066,578

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC.
Condensed Notes to Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The accompanying unaudited financial statements have been prepared by Criticare Systems, Inc. (the "Company") pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and, in the opinion of the Company, include all adjustments necessary for a fair statement of results for each period shown. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such SEC rules and regulations. The Company believes that the disclosures made are adequate to prevent the financial information given from being misleading. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in the Company's latest annual report and previously filed Form 10-K. Certain amounts from the fiscal 2002 financial statements have been reclassified to conform to the 2003 presentation.

2. Inventory Valuation

Inventory is stated at the lower of cost or market, with cost determined on the first-in, first-out method. Components of inventory consisted of the following at September 30, 2003 and June 30, 2003, respectively:

	September 30, 2003	June 30, 2003
Component parts	\$ 2,981,099	\$ 2,762,803
Work in process	664,566	811,906
Finished units	4,127,245	4,172,499
Total inventories	7,772,910	7,747,208
Less: reserve for obsolescence	1,495,000	1,400,000
Net inventory	\$ 6,277,910	\$ 6,347,208

3. Investments

During fiscal 2003, the Company completely liquidated its position in its Immtech International, Inc. (Immtech) common stock. In the first quarter of fiscal 2003 ended September 30, 2002, the Company sold 50,000 shares and realized a gain of \$241,746 that was included in other income in the accompanying consolidated statement of operations. The remaining 406,374 shares of Immtech stock after this sale were sold in the second and third quarters of fiscal 2003.

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4. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	September 30, 2003	June 30, 2003
Machinery and equipment	\$ 2,308,061	\$ 2,264,697
Furniture and fixtures	919,408	919,077
Leasehold improvements	212,229	212,229
Demonstration and loaner monitors	1,253,148	1,346,459
Production tooling	3,670,314	3,617,345
Property, plant and equipment cost	8,363,160	8,359,807
Less: accumulated depreciation	6,298,126	6,266,399
Property, plant and equipment - net	\$ 2,065,034	\$ 2,093,408

On August 30, 2002, the Company sold its building in Waukesha, Wisconsin and leased back approximately 62% of the building's square footage. The building was sold for \$4,000,000 and a gain of \$41,208 was realized on the sale

after the payment of commissions and fees and the funding of \$105,396 in capitalized build out costs needed to split the building into two leasable spaces. The proceeds from the sale were used to retire the \$3,182,160 of debt on the Company's balance sheet at August 30, 2002 and increased the Company's cash position by approximately \$500,000.

5. Contingencies

The import and export rules applicable to all United States companies engaged in international business transactions contain compliance guidelines. Violations may result in civil or criminal penalties, or both, as well as the potential loss of export privileges.

On August 6, 2002, in part due to the new regulations imposed under the Sarbanes-Oxley Act, the Company initiated an internal review of its import and export procedures. On August 28, 2002, senior management of the Company became aware of previous events that may have violated United States import/export laws and regulations. Senior management of the Company immediately authorized an internal audit of these possible violations, focusing on the sale of medical equipment directly or indirectly into an embargoed country and possible marking issues.

The factual investigation pursuant to the internal audit is complete, no additional compliance issues arose, and no material marking issues were identified as a result of the investigation.

Subsequently, the Company has taken action to adopt and implement a written compliance program with respect to applicable import/export rules. The Company has also undertaken a voluntary disclosure with the relevant government agencies and has filed its completed internal audit report and all requested documents. Although there is no assurance, based upon the results of the completed internal audit and precedents, the Company believes a negotiated settlement of any violations will not have a material adverse effect on the Company. In addition, the Company does not believe that the audit result supports the denial of export privileges; however, any such penalty would have a material adverse effect on the Company's business. The Company further believes that the voluntary disclosure, along with other internal actions taken, will serve to mitigate any potential adverse consequences that otherwise might accrue.

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6. Guarantees

Criticare Integration, Inc., a wholly owned U.S. subsidiary of the Company, was incorporated on April 8, 2003 to supply medical equipment and supplies to medical facilities in countries in the Black Sea Economic Zone (Albania, Armenia, Azerbaijan, Bulgaria, Georgia, Romania, and the Ukraine). The Company had set up a standby letter of credit for \$300,000 on behalf of a Romanian company it is working with in connection with this new venture. The standby letter of credit served as a guarantee for a \$2,000,000 line of credit that had been extended by a large Austrian bank to the Romanian company to fund this project. The standby letter of credit was to expire on November 15, 2003. The line of credit was no longer deemed necessary to fund the project and was therefore cancelled prior to expiration. The related standby letter of credit from the Company guaranteeing the line of credit was also cancelled on October 20, 2003.

The Company also maintains a second standby letter of credit for \$300,000 on behalf of the Romanian company that serves as a guarantee to fund borrowings by the Romanian company used to set up and market this project. This standby letter of credit was to expire on November 1, 2003, but was renewed through November 1, 2004 on October 16, 2003. This standby letter of credit would only be called if the cash flows from the project were not adequate to fund these costs and the Romanian company would not be able to retire the debt. The value of this remaining guarantee that was renewed was not material to the Company's financial statements.

7. Stock Options

The Company has adopted the disclosure-only provisions of SFAS No. 123, Accounting for Stock-Based Compensation and SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. If the Company had elected to recognize compensation cost for the options granted for the three months ended September 30, 2003 and 2002, consistent with the method prescribed by SFAS No. 123, net loss and net loss per share would have been changed to the pro forma amounts indicated below:

	Three Months ended September 30	
	2003	2002
Net loss as reported	\$ (391,730)	\$ (291,651)
Net loss pro forma	\$ (393,564)	\$ (291,651)
Basic and diluted net loss per share as reported	\$ (0.04)	\$ (0.03)
Basic and diluted net loss per share pro forma	\$ (0.04)	\$ (0.03)

The fair value of stock options used to compute pro forma net loss and net loss per share is the estimated present value at the grant date using the Black-Scholes option-pricing model.

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CRITICARE SYSTEMS, INC.
Management's Discussion and Analysis of
Results of Operations and Financial Condition
Three Months Ended September 30, 2003 and 2002

Results of Operations

Net sales for the three months ended September 30, 2003 were up slightly from the same period in the prior year. The higher sales were driven by a 4.6% increase in the number of units shipped and a 3.1% increase in the average sales price per unit due to sales mix and increased pricing on certain units and more than offset a \$368,812 decrease in accessory sales in the current period. Consistent with the Company's strategy to diversify its business from traditional vital signs monitoring, shipments of its recently released anesthesia monitoring products increased sales \$198,981 and together with a \$179,805 increase in defibrillator sales in the current period more than offset basically flat sales of the Company's traditional vital signs monitors.

The gross profit percentage of 40.4% for the three months ended September 30, 2003 improved from 38.0% for the same period in the prior year. Lower manufacturing overhead spending and improved pricing on sales of the Company's 8100 vital signs monitors were the major contributors to the higher margins in the current period.

Operating expenses for the three months ended September 30, 2003 increased \$96,168 from the same period in the prior year as a \$180,486 increase in sales and marketing expenses more than offset an \$84,318 combined reduction in research, development and engineering expenses and administrative expenses. The higher expenses in sales and marketing were due mainly to an \$88,269 increase in advertising and sales promotion spending to continue to aggressively market its new line of anesthesia monitoring products, a \$61,184 increase in dealer commissions, and a \$38,090 increase in trade show spending. The higher dealer commissions were driven by increased sales at domestic alternate care sites where the Company utilizes a dealer network to distribute its products. The higher trade show

spending was a timing issue only, as a large domestic trade show was held in the fiscal first quarter ended September 30, 2003 in the current fiscal year but was held in the fiscal second quarter ended December 31, 2002 in the prior year.

Total other income for the three months ended September 30, 2003 decreased \$180,971 from the same period in the prior year. Total other income in the prior year period included the recognition of a \$241,746 gain on the sale of 50,000 shares of the Company's Immtech International, Inc. stock and a \$41,208 gain on the sale of the Company's building. These gains were partially offset by the elimination of \$91,533 in interest expense in the current period due to the retirement of the long-term debt on the Company's facility from the August 30, 2002 sale of its building.

The 3.3% increase in operating expenses and the \$180,971 reduction in total other income more than offset the slightly higher sales and improved gross profit performance for the three months ended September 30, 2003, resulting in a \$391,730 loss that was approximately \$100,000 larger than the \$291,651 loss recognized for the same period in the prior year.

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Liquidity and Capital Resources

As of September 30, 2003, the Company had a cash balance of \$3,866,322 that was \$149,876 higher than its fiscal 2003 year-end balance at June 30, 2003 of \$3,716,446. The Company continues to maintain a long-term bank debt free balance sheet since August 30, 2002 when it sold its building and used the proceeds from the sale to retire the long-term bank debt on the facility.

The Company increased its cash position by \$149,876 for the three months ended September 30, 2003, despite generating a net loss of \$391,730 during the period, as non-cash charges totaling \$242,280 and a \$220,759 reduction in total receivables more than offset capital spending of \$96,664.

The Company believes all capital and liquidity requirements for the remainder of fiscal 2004 will be satisfied by cash generated from operations and its current cash balances. The Company's \$4,000,000 line of credit expires in November 2003. The Company and the bank have agreed to extend the line of credit at a reduced amount of \$2,500,000 subject to the completion of final loan documentation. At September 30, 2003 there were no borrowings outstanding under this line of credit.

Forward Looking Statements

A number of the matters and subject areas discussed herein that are not historical or current facts deal with potential future circumstances and developments. These include anticipated product introductions, expected future financial results, liquidity needs, financing ability, management's or the Company's expectations and beliefs and similar matters discussed in Management's Discussion and Analysis or elsewhere herein. The discussions of such matters and subject areas are qualified by the inherent risk and uncertainties surrounding future expectations generally, and also may materially differ from the Company's actual future experience.

The Company's business, operations and financial performance are subject to certain risks and uncertainties which could result in material differences in actual results from management's or the Company's current expectations. These risks and uncertainties include, but are not limited to, general economic conditions, demand for the Company's products, costs of operations, the development of new products, the reliance on single sources of supply for certain components in the Company's products, government regulation, health care cost containment programs, the effectiveness of the Company's programs to manage working capital and reduce costs, competition in the Company's markets, compliance with product safety regulations and product liability and product recall risks, risks relating to international sales and compliance with U.S. export regulations, unanticipated difficulties in outsourcing the

manufacturing of the majority of its products to foreign manufacturers and risks related to foreign manufacturing, including economic and political instability, trade and foreign tax laws, production delays and cost overruns and quality control.

Quantitative and Qualitative Disclosures about Market Risk

The Company has a demand line of credit facility with a commercial bank with interest payable monthly at 25 basis points above the bank's reference rate. The Company had no borrowings outstanding under this bank facility at September 30, 2003 and June 30, 2003. Due historically to the lack of need to borrow from this credit facility and due to the Company's current cash position, the Company is not subject to financial risk on this obligation if interest rates in the market change significantly.

The Company's net sales are primarily denominated in United States dollars, except for a small amount of net sales from the Company's operation in India denominated in Indian rupees. As a result, part of the Company's accounts receivable are denominated in rupees and translated into U.S. dollars for financial reporting purposes. A 10% change in the exchange rate of the U.S. dollar with respect to the Indian rupee would not have a material adverse effect on the Company's financial condition or results of operations. The Company does not use any hedges or other derivative financial instruments to manage or reduce exchange rate risk.

Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Vice President - Finance, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Vice President - Finance concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company required to be included in the Company's periodic filings with the Securities and Exchange Commission. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving the desired control objectives and based upon the evaluation described above, the Company's Chief Executive Officer and Vice President - Finance concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

There was no change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

3.1 Restated Certificate of Incorporation of the Company (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

3.2 By-Laws of the Company (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

4.1 Specimen Common Stock certificate (incorporated by reference to the Registration Statement filed on Form S-1, Registration No. 33-13050).

4.2 Rights Agreement (incorporated by reference to the Company's Current Report on Form 8-K filed on April 18, 1997).

31.1 Certification of Emil H. Soika, President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Michael J. Sallmann, Vice President - Finance and Secretary (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32* Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.

* This Certification is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

(b) Reports on Form 8-K: On September 15, 2003 the Company furnished a current report on Form 8-K pursuant to Items 9 and 12 regarding the Company's press release on September 12, 2003 with respect to the Company's results for its fiscal year ended June 30, 2003.

SIGNATURES

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.

CRITICARE SYSTEMS, INC.
(Registrant)

Date: November 13, 2003
Michael J. Sallmann
Vice President - Finance
(Chief Accounting Officer and

BY /s/ Michael J. Sallmann

Duly Authorized Officer)