CRITICARE SYSTEMS INC /DE/
Form 10-K
September 29, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

(Mark One)

[x] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended June 30, 2003

[ ] 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 No.)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
NA	NA

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Securities registered pursuant to Section 12(g) of the Act:

Voting Common Stock, $.04 Par Value
(together with associated Preferred Stock Purchase Rights)
(Title of class)

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 [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).
Yes [ ] No [X]

The aggregate market value of the voting common stock held by nonaffiliates of the registrant as of December 31, 2002 (the last business day of the registrant s most recently completed second fiscal quarter) was $28,387,817. Shares of voting common stock held as of December 31, 2002 by any person who was an executive officer or director of the registrant as of December 31, 2002 and any person who beneficially owned 10% or more of the outstanding voting common stock as of December 31, 2002 have been excluded from this computation because such persons may be deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

On August 31, 2003, there were 11,072,846 shares of the registrant's $.04 par value voting common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Annual Meeting of the Stockholders of the Registrant to be held November 14, 2003 are incorporated by reference into Part III of this report.

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PART I

Item 1. BUSINESS.

Criticare Systems, Inc. (the "Company" or "Criticare") designs, manufactures and markets vital signs and gas monitoring instruments and related noninvasive sensors used to monitor patients in many healthcare environments. Since a patient's oxygen, anesthetic gas and carbon dioxide levels can change dramatically within minutes, causing severe side effects or death, continuous monitoring of these parameters is increasing. The Company's monitoring equipment improves patient safety by delivering accurate, comprehensive and instantaneous patient information to the clinician. The Company's products also allow hospitals to contain costs primarily by substituting cost-effective reusable pulse oximetry sensors for disposable sensors, controlling the use of costly anesthetics and increasing personnel productivity.

To meet the needs of end-users in a wide variety of patient environments, the Company has developed a broad line of patient monitors which combine one or more of its patented or other proprietary technologies, for monitoring oxygen saturation, carbon dioxide and anesthetic agents, with standard monitoring technologies that provide electrocardiogram ("ECG"), invasive and noninvasive blood pressures, temperature, heart rate and respiration rate. In addition, the Company's VitalView telemetry system allows one nurse to monitor up to eight patients simultaneously from a convenient central location. This allows hospitals to move out of the intensive care unit those patients that require continuous monitoring, but do not need all of an intensive care unit's extensive and costly personnel and equipment resources.

According to the guidance set by Statement of Financial Accounting Standards No. 131, the Company operates in one business segment in the healthcare environment. The chief operating decision maker does not utilize segmented financial statements in making decisions about resource allocation because the business activities that generate revenue do not have expenses specifically associated with them. Therefore, no segment data is disclosed in the notes to the financial statements in Item 8. However, the Company's customer base is differentiated by region (see note 11 in the notes to the financial statements in Item 8 for an analysis of sales by geographic area).

The Company was incorporated under the laws of the State of Delaware in October 1984.

Products

Criticare markets a broad range of vital signs and gas monitoring products designed to address the needs of a variety of end-users in different patient environments. Criticare's monitors display information graphically and numerically. Many of the Company s new products, as well as

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those in development, focus on anesthesia related monitoring, as management believes this is a high growth area with relatively few competitors. All Criticare monitors incorporate adjustable visual and audible alarms to provide reliable patient-specific warnings of critical conditions, and most of the Company's monitors record up to 60 hours of trend data. Criticare monitors are available with printer capability to provide permanent records of patient data.

Poet Plus 8100 Vital Signs Monitors. The full-featured CSI 8100 Vital Signs Monitor provides maximum flexibility for hospital, transport and outpatient care settings. The unit's custom configurations include ECG, ComfortCuff noninvasive blood pressure, DOX digital oximetry, heart rate, temperature, respiration rate, and nurse call interface. Optional features include CO_2 and CO_2/O_2 monitoring and an integrated printer. The 8100 is well suited for busy departments that require basic vital signs monitoring to conscious sedation.

Poet IQ 8500 and Poet IQ2 8500Q Anesthetic Gas Monitors. The Poet IQ 8500 gas monitor is used in conjunction with the Poet Plus 8100 vital signs monitor to provide a unique combination of leading edge vital signs technology and anesthesia gas monitoring in a compact, modular system. The Poet IQ2 8500Q gas monitor provides leading edge

anesthesia gas monitoring in a compact stand alone monitor. The operating systems of both monitors consist of an integrated, solid state module based upon a proprietary infrared technology developed by Criticare. They automatically monitor up to five anesthetic agents plus nitrous oxide, oxygen, and carbon dioxide. The systems also utilize a unique, disposable water trap component that is also proprietary to the Company. These products were released in March 2003 and are being marketed as configurable systems for applications by original equipment manufacturers ("OEMs") and as Criticare branded products. The systems reliable performance, ease of use, flexible design, and affordable cost make them the ideal monitoring solutions for anesthesia applications in hospitals and surgical centers.

Model 503DX, 504+, and 504DX Pulse Oximeters. Criticare's complete line of pulse oximeters meets the needs of virtually all clinical environments, including: adult, pediatric and neonatal intensive care units, operating rooms, emergency rooms, nursing homes, physicians' offices and ambulances. The line is designed to provide accuracy and convenience at a competitive cost to the end-user.

Model 506DX and 507ELC Patient Monitors. The 506DX and 507ELC series of monitors are comprised of small, compact, portable, full-featured vital signs monitors configured to meet specific clinical needs. The 506DX combines oxygen saturation, noninvasive blood pressure and temperature and is ideal for spot checking or continuously monitoring patients vital signs. The 507ELC series combines ECG, oxygen saturation, noninvasive blood pressure, temperature, and respiration for a complete vital signs monitor for physician offices, clinics, and hospital applications.

VitalView Central Monitoring Station. The VitalView central station makes it possible for one nurse or technician to monitor numerous patients simultaneously. The VitalView can receive, display and store data from a wide variety of Criticare monitors and patient-borne multiple parameter telemetry devices for continuous, comprehensive vital signs monitoring.

Pulse Oximetry Sensors. Criticare has designed proprietary, noninvasive sensors that can be used on any patient, from a premature infant to a full-grown adult. Criticare's line of reusable pulse oximetry sensors offers users significant cost savings compared to disposables. Criticare's reusable sensors generally last longer than the one-year warranty period and are easily and inexpensively cleaned between uses. Criticare's reusable sensors include a finger sensor for routine applications and a multisite sensor for increased placement flexibility. The multisite sensor is fully immersible, allowing for sterilization between patients. The Company also sells a range of disposable sensors designed for single use in cases where the facility would prefer to use a patient charge disposable product.

WaterChek /Chek-Mate Filter System. The Company's patented, disposable Water Chek system separates a patient's respiratory secretions from a breath sample before it enters the gas monitor(s) for analysis. The Company's proprietary, disposable Chek-Mate filter enhances the removal of moisture from the sample, while preventing cross-contamination. This system allows the monitor to operate effectively regardless of humidity or patient condition. The self-sealing feature also protects the healthcare provider from potential contamination.

Automatic External Defibrillator. In the fourth quarter of fiscal 2003 the Company entered into a distribution agreement with a manufacturer of automatic external defibrillators that will allow Criticare to sell their defibrillators in the markets in which Criticare has an established presence. This newly developed system is the only public access defibrillator designed for people exhibiting symptoms of cardiac arrest, making earlier intervention possible. The defibrillator will safely monitor the victim and advise whether a shock is necessary. After the person is successfully defibrillated, the electrodes can remain attached to continuously monitor the person during transport in the ambulance to the hospital. The agreement for the Company to distribute this new defibrillator replaces a distributor agreement

previously set up with another manufacturer of defibrillators.

Marketing and Sales

Domestic Sales. At August 31, 2003, the Company's domestic sales force consisted of six employees and 91 independent dealers. The Company's sales force and independent dealers market the Company's products to many different types of medical facilities such as hospitals, surgery centers, nursing homes and physician offices. The Company sells its higher-end monitors (anesthetic agent monitors and Vital View Central Station) principally to hospitals whereas the vital signs and pulse oximeters are sold primarily in non-hospital settings.

In June 1999 the Company began to focus on selling to OEMs with the hiring of a senior manager to lead this effort. Modules and stand-alone monitors were developed and marketed for blood pressure, pulse oximetry, respiration rate, and anesthetic gases for specific OEM customers. OEM business has become a significant sales channel for the Company and is expected to be a primary driver of growth in future periods. An OEM customer, Alaris Medical Systems, Inc., is the Company s largest customer and has generated 13.0%, 13.4%, and 12.2% of the Company s total revenue in fiscal 2003, 2002, and 2001, respectively.

International Sales. One of the Company's principal marketing strategies has been to target international markets, particularly Europe, Latin America and the Pacific Rim countries. During fiscal 2003, Criticare sold its products, principally to hospitals, in over 95 countries through over 95 independent dealers.

In order to expand its business in China and Taiwan, in fiscal 2002 the Company changed its distributor in these countries. This distributor will now manufacture, sell, and service Criticare labeled product in China and Taiwan. Also in fiscal 2002, the Company entered into a distribution agreement with a Romanian company that will distribute Criticare labeled product in the Black Sea Economic Zone, including Romania, Bulgaria, Ukraine, Belarus, Greece, Turkey, Serbia, Croatia, Slovenia, Slovakia, and Hungary. The Company expects to increase its international sales by entering and servicing these high growth, developing markets.

Most of the Company's international order processing, invoicing, collection and customer service functions are handled directly from the Company's headquarters in Waukesha, Wisconsin. Criticare believes demand for the Company's products in international markets is primarily driven by cost containment concerns, and increased interest in using quality patient monitoring products for improved patient management.

In fiscal 2003, 41% of Criticare's net sales, or $11.6 million, was attributable to international sales, of which approximately 67% was from sales in Europe and the Middle East, 14% was from sales to Pacific Rim countries and 19% was from sales to Canada and Central and South America. In fiscal 2002 and 2001, 39% and 41%, respectively, of Criticare's net sales were attributable to international sales. Other than inventory and accounts receivable for the Company s operation in India totaling approximately $1.5 million, there are no material identifiable assets of the Company located in foreign markets. The Company primarily sells its products in United States dollars and is therefore not subject to currency risks other than currency fluctuations from its operation in India; however, an increase in the value of the United States dollar relative to foreign currencies could make the Company's products less price competitive in those markets. In addition, significant devaluation of certain foreign currencies could adversely affect the collectibility of

accounts receivable from international customers. The Company analyzes this risk before making shipments to countries it views as unstable.

Service, Support and Warranty. Criticare believes that customer service is a key element of its marketing program. At August 31, 2003, the Company had a customer service and technical support staff of 20 people at its Waukesha, Wisconsin facility. Customer service support is available 24 hours a day, seven days a week, with the majority of customers technical problems being resolved over the telephone. The customer service staff also provide periodic training and education of the direct sales force who in turn provide training to the dealers and end-users.

Criticare's monitors and sensors are warranted against defects for one year. If a problem develops with a Criticare product while under warranty, the Company typically provides a replacement unit until the product can be repaired at the Company's facility. The Company offers extended warranties and service contracts on all of its monitors.

Manufacturing

Historically, Criticare has manufactured and assembled its products internally, principally at the Company's facility in Waukesha, Wisconsin. Due mainly to pricing pressures on monitoring systems worldwide, in fiscal 2001 the Company entered into agreements with two offshore contract manufacturing firms located in Ireland and Taiwan, respectively, that exclusively manufacture medical devices in a regulated environment. The contract manufacturing firm in Taiwan also has manufacturing capabilities in China and a portion of Criticare s production is being transitioned to China to continue to receive favorable pricing. The Company works closely with these two firms to maintain product quality and reliability. These two firms perform the same rigorous quality control testing at their facilities that Criticare had done in the past at its own facility. With the majority of the Company s manufacturing outsourced as of the end of calendar 2001, Criticare concentrates on product enhancements and new product development, customer service, and increased involvement with its OEM customers. The Company anticipates that it will continue limited production of new products internally during the development phase and for a short period after commercial introduction until production can be effectively transitioned to offshore manufacturers.

Any inability of these offshore manufacturers to deliver products on a timely basis could have a material adverse effect on the Company. However, each of these manufacturers has the ability to produce the majority of the Company s products, in addition to the dual manufacturing capabilities that the Taiwanese company has to produce product in both Taiwan and China. Therefore, the Company is not totally reliant on a single plant or single source to supply product. This factor, combined with the Company s ability to continue to manufacture at its headquarters in Waukesha, Wisconsin, reduces the Company s risk of supply interruption.

The Company has achieved certification under the International Organization for Standardization s (ISO) standards 9001 and 9002. Each of the offshore contract manufacturing firms has achieved certification under ISO's standard 9001. See "Regulation."

Research, Development and Engineering

Criticare has focused its research, development and engineering expenditures on products designed to meet identified market demands. The Company seeks to apply its expertise in gas monitoring, vital signs monitoring, and related sensor technology to develop new products and adapt existing products for new markets. At August 31, 2003, the Company had an in-house research, development and engineering staff of 24 people. The Company's research,

development and engineering expenditures were $2.7 million in fiscal 2003, $2.3 million in fiscal 2002 and $2.4 million in fiscal 2001.

Research and development efforts for the last three fiscal years has focused on the development and release of the 8500 series monitors which feature automatic identification and quantification of all five approved anesthetic agents and refinements to the 8100 product line that was released late in fiscal 2000.

Competition

The markets for the Company's products are highly competitive. Many of Criticare's competitors, including its principal competitors described below, have greater financial resources, more established brand identities and reputations, longer histories in the medical equipment industry and larger and more experienced sales forces than Criticare. In these respects, such companies have a competitive advantage over Criticare. The Company competes primarily on the basis of product features, the quality and value of its products (i.e. , their relative price compared to performance features provided) and the effectiveness of its sales and marketing efforts. The Company believes that its principal competitive advantages are provided by its focus on cost containment, provided in part by its outsourcing a large portion of its manufacturing, its patented and other proprietary technology and software for noninvasive, continuous monitoring of oxygen, anesthetic gases, carbon dioxide and noninvasive blood pressure, the efficiency and speed of its research and development efforts, and its established international presence.

The Company believes that the worldwide anesthetic agent and carbon dioxide monitor markets are comparatively fragmented, with Datex/Ohmeda (which is being acquired by General Electric) as the principal competitor. The Company's principal competitors in the domestic gas monitor market include Datex/Ohmeda and Andros. The market for vital signs monitors includes competitors such as General Electric, Philips, Siemens A.G., Datex/Ohmeda, Welch Allyn, and Spacelabs Medical, Inc. (which is being divested by Instrumentarium Oyj).

The Company believes that its principal competitors in Western Europe and the Pacific Rim countries are General Electric, Siemens A.G., Philips, and Datex/Ohmeda.

Regulation

As a manufacturer of medical diagnostic equipment, the Company is regulated by the FDA and similar foreign governmental agencies. In producing its products, the Company must comply with a variety of regulations, including the good manufacturing practices regulations of the FDA. In addition, it is subject to periodic inspections by this agency. If the FDA believes that its legal requirements have not been fulfilled, it has extensive enforcement powers, including the ability to ban or recall products from the market and to prohibit the operation of manufacturing facilities. The Company believes its products comply with applicable FDA regulations in all material respects. In addition, the Company received ISO 9002 certification on April 29, 1993 and ISO 9001 certification on July 8, 1994.

Under the Federal Food, Drug and Cosmetic Act, as amended, all medical devices are classified as Class I, Class II or Class III, depending upon the level of regulatory control to which they will be subject. Class III devices, which are the most highly controlled devices, are subject to premarket approval by the FDA prior to commercial distribution in the United States.

The Company's current products have not been subject to the FDA's comprehensive premarket approval requirements, but are generally subject to premarket notification requirements. If a new device is substantially equivalent to a device

that did not require premarket approval, premarket review is satisfied through a procedure known as a "510(k) submission," under which the applicant provides product information supporting its claim of substantial equivalence. The FDA may also require that it be provided with clinical trial results showing the device's safety and efficacy.

The Company believes that the products it is currently developing generally will be eligible for the 510(k) submission procedure and, therefore, will not be subject to lengthy premarket approval procedures. However, these products are still being developed and there can be no assurance that the FDA will determine that the products may be marketed without premarket approval.

Criticare seeks, where appropriate, to comply with the safety standards of Underwriters' Laboratories and the Canadian Standards Association and the standards of the European Community. To date, the Company has not experienced significant regulatory expense or delay in the foreign markets in which it sells its products. Industry and professional groups such as the American Society of Anesthesiologists, to the extent they have the power to mandate certain practices or procedures as part of their profession's standard of care, are also a source of indirect regulation of the Company's business.

Patents and Trademarks

The Company believes one of its principal competitive advantages is provided by its patented and other proprietary technology including its sensor technology, infrared specific anesthetic gas monitoring technology, UltraSync signal processing software and disposable respiratory secretion filter system. The Company has 16 issued U.S. patents and three patent applications pending. The Company's U.S. patents expire between 2004 and 2019. Criticare also has two issued foreign patents and 12 foreign patent applications pending. There is no assurance that any patents held or secured by the Company will provide any protection or commercial or competitive benefit to the Company. There is also no assurance that the Company's products will not infringe upon patents held by others. The Company is the owner of United States trademark registrations for "POET", "MPT", "REMOTEVIEW", "MICROVIEW", VITALVIEW , SCHOLAR , and WATERCHEK .

The Company also relies upon trade secret protection for certain of its proprietary technology. Although the Company requires all employees to sign confidentiality agreements, no assurance can be given that such agreements can be effectively enforced or that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to or disclose the Company's trade secrets.

Employees

At August 31, 2003 Criticare had 88 employees, including 24 in research, development and engineering, 20 in customer service, 14 in manufacturing and operations, 12 in administration, 13 in sales and marketing, and five in quality control. Criticare also utilizes four international country managers that work as independent contractors to support its international sales efforts.

Many of the Company's technical employees are highly skilled. The Company believes that its continued success depends in part on its ability to continue to attract qualified management, marketing and technical personnel. None of the Company's employees are subject to a collective bargaining agreement. The Company believes that its relations with its employees are good.

Backlog

Criticare's backlog on June 30, 2003 and 2002 was $407,695 and $699,450 respectively. Criticare generally delivers its products out of inventory when specified by the customer. The Company does not believe that its backlog at any date is indicative of its future sales.

Item 2. PROPERTIES.

In August 2002, the Company sold its 60,000 square foot building in Waukesha, Wisconsin for $4,000,000 and leased back approximately 37,000 square feet of this building to serve as the Company s headquarters, warehouse, manufacturing, research and development and service facility. The proceeds from the sale were used to retire the mortgage note on the facility. The lease expires on August 30, 2007, with an option for the Company to extend for an additional three years, with rent totaling $22,423 per month for the first year of the lease and annual increases approximating 3% in years two, three and five of the lease.

Item 3. LEGAL PROCEEDINGS.

In the normal course of business Criticare may be involved in various legal proceedings from time to time. Criticare does not believe it is currently involved in any claim or action the ultimate disposition of which would have a material adverse effect on Criticare.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended June 30, 2003.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Company's common stock is traded on the Nasdaq National Market (Symbol CXIM). As of June 30, 2003, there were approximately 231 holders of record of the common stock. The Company has never paid dividends on its common stock and has no plans to pay cash dividends in the foreseeable future. The Company s credit agreement prohibits any redemption of shares of common stock or any distribution or dividend to the Company s stockholders.

	Year Ended June 30,			
	2003		2002	
Quarter Ended:	High	Low	High	Low

September 30	$ 3.99	$ 2.48	$ 4.68	$ 3.30
December 31	$ 3.62	$ 2.41	$ 5.23	$ 4.00
March 31	$ 3.77	$ 2.41	$ 4.70	$ 3.50
June 30	$ 3.15	$ 2.24	$ 5.81	$ 4.00

Item 6. SELECTED FINANCIAL DATA.

The following table sets forth selected financial data with respect to the Company for each of the periods indicated, which should be read along with our consolidated financial statements and the notes to those statements and with Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended June 30,				
	2003	2002	2001	2000	1999
Net sales	$ 28,562,943	$ 26,219,618	$ 27,736,304	$ 27,154,236	$ 28,512,507
Net loss	(938,596)	(1,425,181)	(178,232)	(186,388)	(4,388,171)
Net loss per common share-- basic and diluted	$ (0.08)	$ (0.13)	$ (0.02)	$ (0.02)	$ (0.51)
Average shares outstanding-- basic and diluted	11,071,735	10,876,818	10,171,394	8,694,918	8,581,863
Stockholders' equity	$ 15,034,208	$ 18,387,067	$ 21,005,816	$ 18,798,952	$ 12,711,709
Long-term obligations	38,662	3,151,879	3,270,131	3,552,474	4,014,356
Working capital	12,895,476	15,464,899	17,995,488	16,257,780	10,340,014
Total assets	18,762,327	25,474,256	29,871,854	27,210,867	24,041,987

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Results of Operations

The following table sets forth, for the periods indicated, certain items from the Company's Consolidated Statements of Operations expressed as percentages of net sales.

	Percentage of Net Sales Years Ended June 30,		
	2003	2002	2001

Net sales	100.0%	100.0%	100.0%
Cost of goods sold	63.5	62.8	59.4
Gross profit	36.5	37.2	40.6
Operating expenses:			
Sales and marketing	22.3	21.5	23.0
Research, development and engineering	9.6	8.9	8.8
Administrative	13.4	11.4	9.1
Total	45.3	41.8	40.9
Loss from operations	(8.8)	(4.6)	(0.3)
Interest expense	(0.3)	(0.9)	(0.9)
Interest income	0.2	0.3	0.5
Foreign currency exchange gain (loss)	0.3	(0.5)	--
Gain on sale of stock	4.5	--	--
Other income	0.9	0.3	--
Loss before income taxes	(3.2)	(5.4)	(0.7)
Income tax provision	--	--	--
Net loss	(3.2)%	(5.4)%	(0.7)%

Fiscal Year Ended June 30, 2003 Compared to June 30, 2002

Net sales of $28.6 million for the fiscal year ended June 30, 2003 were up 8.9% from the $26.2 million of sales generated in fiscal 2002. A 12.5% increase in international sales and a 6.6% increase in domestic sales drove revenue higher in the current fiscal year. An 8.8% increase in the number of units shipped and an 8.5% increase in the average selling price per unit, partially offset by a 14.2% decrease in accessory sales, contributed to the higher revenue between years. OEM sales in fiscal 2003 increased for the fourth consecutive year to $5,457,000 and represented 19.1% of total sales, compared to $5,103,000 in fiscal 2002.

The gross profit percentage of 36.5% realized in fiscal 2003 decreased from the 37.2% generated in the prior year. The main contributor to the lower margins was $1,752,000 of charges to cost of goods sold to increase the obsolescence reserve for inventory associated with discontinued products that was disposed of in the current year and for potential obsolete inventory that was still in stock at fiscal year-end. These charges represented 6.1% of net sales in fiscal 2003 and more than offset the favorable impact from higher sales that resulted in a better utilization of fixed manufacturing costs when compared to the prior fiscal year.

The majority of the charges to cost of goods sold ($1,122,000) to increase the obsolescence reserve was recorded in the Company s fiscal fourth quarter ended June 30, 2003. In the fourth quarter the Company received revised forecasts from two key business partners that significantly reduced the expected demand for two products for which the Company maintained large inventories of component parts. The Company also released its new line of anesthesia

monitoring products in its fiscal fourth quarter, increasing the risk of obsolescence of component parts maintained for its old line of anesthesia monitoring products. Mainly due to these two events that arose in the fourth quarter, the Company increased its reserve for obsolete inventory to $1.4 million from its $464,000 balance at the end of the fiscal third quarter ended March 31, 2003. This increase in the obsolescence reserve in the fourth quarter reduced gross margins to 24.1% and increased the loss for the fourth quarter to $1,286,799.

Total operating expenses in fiscal 2003 were almost $2.0 million higher than the prior year and more than offset the favorable impact of higher sales in the current year. Administrative expenses increased $839,248 due mainly to legal and consulting fees related to the internal review conducted by the Company of its import and export procedures that totaled approximately $495,000. Also contributing to higher administrative expenses in 2003 were a final settlement of $150,000 made to the Company s former CEO and founder to satisfy past severance obligation issues and $105,000 of increased spending on business and health insurance, utilities, and investor related expenses.

Sales and marketing expenses were $744,549 higher in fiscal 2003 than the prior year due mostly to a $330,000 increase in employee and dealer commissions driven by the higher sales and an increase in bad debt expense of $221,000 between years. In fiscal 2002, recoveries of bad debts expensed in prior years more than offset additional provisions expensed, resulting in a credit of bad debt expense of $183,000 compared to $38,000 of bad debt expense recognized in fiscal 2003. In addition, a $139,000 increase in combined trade show, travel, and advertising spending to support the rollout of the Company s new anesthesia products contributed to the higher sales and marketing expenses in the current year.

Research, development, and engineering expenses were up $397,181 in the current year over the prior year due mostly to a $360,000 increase in combined labor, employee benefits, and project spending costs incurred to launch the Company s new line of proprietary anesthesia monitoring products.

Total other income was almost $1.8 million higher in fiscal 2003 than the prior year which offset the majority of the increase in operating expenses, resulting in a bottom line net loss of $938,596 that was almost $500,000 lower than the $1,425,181 net loss in the prior year. The other income consisted mainly of a $1,290,252 gain recognized on the sale of the Company s investment in Immtech International, Inc., $93,000 in profit recognized on a medical integration project in Romania, and a $41,208 gain on the sale of the Company s building. In addition, the Company realized an $82,403 foreign currency exchange gain in the current year related to the Company s operation in India compared to a $119,188 foreign currency exchange loss recognized in the prior year. The Company retired its long-term bank debt in August 2002 by using the proceeds from

the sale of the Company s facility. This bank debt retirement caused a reduction in interest expense of $154,674 over the prior year and, consequently, contributed to higher other income in the current year over the prior year.

Fiscal Year Ended June 30, 2002 Compared to June 30, 2001

Net sales of $26.2 million for the fiscal year ended June 30, 2002 were down 5.5% from $27.7 million in fiscal 2001. A 5.0% reduction in the number of units shipped and a 3.9% decrease in the average selling price per unit were the main contributors to the sales decline between years. A 2.0% increase in accessory sales in fiscal 2002 partially offset the reduced sales volume and lower average selling prices on the Company's monitors and related equipment.

International sales in fiscal 2002 to Criticare s distributors in the United Kingdom (U.K.) and China decreased 36.3% from the prior year and contributed over $1.1 million to the Company s sales decrease between years. Significant

cutbacks in health care spending in the U.K., where only critically important capital expenditures were being made, negatively impacted the Company s sales to its distributor in the U.K. in fiscal 2002. The transition to a new distributor in China in fiscal 2002 resulted in reduced sales in fiscal 2002 as this change was implemented.

Domestic sales in fiscal 2002 were down $499,552 from the prior year, but this was partially offset by higher sales to domestic OEM customers that were up $182,186 in fiscal 2002. The decrease in domestic sales can be attributed to the poor U.S. economy in fiscal 2002 and the events of September 11th, which basically eliminated sales from one of the Company s largest domestic trade shows that was held that week. OEM sales in fiscal 2002 increased for the third consecutive year and represented 19.5% of total company sales in fiscal 2002, consistent with the Company s strategy to increase this segment of its business.

The gross profit percentage of 37.2% realized in fiscal 2002 was down from 40.6% in fiscal 2001. Higher manufacturing costs in the first six months of fiscal 2002 to support the Company s efforts to transition its manufacturing offshore by the end of calendar year 2001 and the lower sales volume between years resulted in an under-utilization of fixed manufacturing costs which contributed to reduced margins in fiscal 2002. Due to the outsourcing of the majority of the Company s products, approximately $509,000 of fixed costs that had previously been classified as manufacturing expenses were included in administrative expenses in fiscal 2002. The favorable impact of this change on margins was offset by a $621,000 increase in the reserve for obsolete inventory that was deemed necessary due to continued high levels of component parts being maintained by the Company after outsourcing the majority of its manufacturing.

Total operating expenses in fiscal 2002 were $385,796 lower than the prior year, despite a $457,611 increase in administrative expenses, due mainly to a $736,196 reduction in

marketing expenses in fiscal 2002. As noted above, the higher administrative expenses were mainly driven by a change in the classification of expenses due to a change in the operations of the business. Certain fixed costs that had been expensed as manufacturing costs in prior years were more appropriately classified as administrative expenses in fiscal 2002. The decrease in marketing expenses was due mostly to a reduction in sales commissions and bonuses earned from lower sales in fiscal 2002. In addition, the elimination of a sales vice president position in the fourth quarter of the prior year resulted in a reduction in marketing salaries and fringe benefits in fiscal 2002.

In addition to the lower sales and reduction in gross profit in fiscal 2002, a $120,526 increase in other expenses in fiscal 2002, due mostly to the recognition of a $119,188 foreign currency exchange loss related to the Company s operation in India, contributed to the $1,425,181 loss generated in fiscal 2002.

Critical Accounting Policies

The Company s discussion and analysis of its financial condition and results of operations are based upon the Company s consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to bad debts, sales returns, inventories, and warranty obligations. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. The Company believes the following accounting policies require its more significant judgments and estimates used in the preparation of its

financial statements.

Revenue Recognition

Revenues and the costs of products sold are recognized as the related products are shipped or installed, if there are significant installation costs. This revenue recognition policy is utilized for shipment of product to customers including both distributors and end-users.

Revenues for integration contracts where Criticare Integration acts as an intermediary to supply medical equipment and supplies to medical facilities in countries in the Black Sea Economic Zone are recognized on a net basis for services rendered upon completion of the transaction giving

rise to the service. Since the activity for these integration services was not material in fiscal 2003, they are included in the accompanying statements of operations as other income.

Estimating Allowances for Doubtful Accounts and Sales Returns

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. Management analyzes specific accounts receivable as well as historical bad debts, customer concentrations, customer credit-worthiness, current economic trends, foreign currency movements, and changes in its customer payment terms when evaluating the allowance for doubtful accounts. If the financial condition of any of the Company s customers were to deteriorate, resulting in impairment of their ability to make payments, additional allowances may be required.

The Company also maintains a sales returns reserve in order to estimate potential future product returns related to current period revenue. Management analyzes historical returns, current economic trends, changes in customer demand, and acceptances of the Company s products when evaluating the adequacy of the sales returns reserve. Significant management judgments and estimates must be made and used in connection with establishing the sales returns reserve in any accounting period. Material differences may result in the timing of the Company s revenue if management made different judgments or utilized different estimates.

Valuation of Inventories

Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out method. The Company maintains a reserve for obsolete inventory that it utilizes to write down inventories for estimated obsolescence or unmarketable inventory equal to the difference between the carrying value of the inventory and the estimated market value. The Company determines the adequacy of the obsolescence reserve by considering historical annual usage of component parts and finished goods as well as assumptions about market conditions and forecasted demand. When items are physically disposed of the amounts are written off against the reserve. If future product demand is lower than expected or if market conditions are less favorable than those projected by the Company, additional charges to increase the obsolescence reserve may be required.

During fiscal 2003, the reserve for obsolete inventory was increased $454,000 to $1,400,000 at June 30, 2003 to provide for potential obsolete inventory associated with discontinued products and excess inventory associated with slow moving parts. During fiscal 2002, the reserve for obsolete inventory was increased by $621,000 to $946,000 at June 30, 2002 due to continued high levels of component parts being maintained by the Company after outsourcing the majority of its manufacturing.

Product Warranty

The Company provides for the estimated cost of product warranties at the time products are shipped based upon its historical experience providing warranty coverage. The Company s warranty obligations are affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. If actual product failure rates, material usage or service delivery costs differ from current projections, revisions to the estimated warranty reserve would be required.

Recently Issued Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board (the "FASB") issued FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Guarantees of the Indebtedness of Others , which addresses the accounting for and disclosure of guarantees. Interpretation No. 45 requires a guarantor to recognize a liability for the fair value of a guarantee at inception. The recognition of the liability is required even if it is not probable that payments will be required under the guarantee. The initial recognition and measurement provisions are effective on a prospective basis for guarantees issued or modified after December 31, 2002. The Company has issued two $300,000 letters of credit on behalf of a third party and as such adopted the provision of Interpretation No. 45. The recognition of the fair value liability of the guarantees did not have a material effect on the financial statements.

In December 2002, the FASB issued SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure , an amendment of SFAS 123, Accounting for Stock-Based Compensation , which requires additional disclosures and provides alternatives for companies electing to account for stock-based compensation using the fair value criteria established by SFAS 123. The Company intends to continue to account for stock-based compensation under the provisions of APB 25. The Company has adopted the required disclosures of SFAS 148 in its financial statements.

In April 2003, the FASB issued SFAS 149, Amendment of Statement 133 Derivative Instruments and Hedging Activities . SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133, Accounting for Derivative Instruments and Hedging Activities . SFAS 149 is generally effective for derivative instruments, including derivative instruments embedded in certain contracts, entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The Company does not expect the adoption of SFAS 149 to have a material impact on its financial position or results of operations.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity . SFAS 150 improves the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity and

requires that those instruments be classified as liabilities (or assets in certain circumstances) in the balance sheet. SFAS 150 also requires disclosures about alternative ways of settling the instruments and the capital structure of

entities all of whose shares are mandatorily redeemable. SFAS 150 is generally effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company does not expect the adoption of SFAS 150 to have a material impact on its financial position or results of operations.

See the Summary of Significant Accounting Policies in footnote one of the Notes to the Consolidated Financial Statements for further explanation of these Statements of Financial Accounting Standards.

Liquidity and Capital Resources

As of June 30, 2003, the Company had a cash balance of $3,716,446 and a long-term debt free balance sheet due to the sale of the Company s building in the current fiscal year. The Company sold its building in Waukesha, Wisconsin in August 2002 for $4,000,000, leased back approximately 62% of its square footage, and used the proceeds from the sale to retire the $3,182,160 of long-term debt on the balance sheet at August 31, 2002. The other significant event favorably impacting cash flows in fiscal 2003 was the sale of all 456,374 shares of the Company s Immtech International, Inc. common stock. The sale of these shares resulted in an increase in cash and a realized gain of $1,290,252 in the current year. The sale of the building and the Immtech shares allowed the Company to retire its long-term bank debt, fund operating activities and capital spending requirements, repurchase 35,100 shares of Criticare common stock in accordance with the stock buyback approved by the Criticare Board of Directors in the third quarter of fiscal 2002, and increase its cash balance by almost $200,000 during fiscal 2003.

The Company s sale of its facility and its investment in Immtech common stock were the main contributors to the $4,309,041 of cash provided by investing activities during fiscal 2003 and more than offset the $3,297,384 of cash used in financing activities and the $808,967 of cash used in operations. Almost $3.2 million of the nearly $3.3 million of cash used in financing activities went to retire the long-term debt outstanding on the Company s building.

At June 30, 2002, the Company had no short-term borrowings and a cash balance of $3,523,070 that was up $160,966 from the $3,362,104 cash balance at the end of fiscal 2001. The Company generated $283,269 of cash from operations as significant reductions in accounts receivables and additional decreases in inventory more than offset the $1,425,181 loss in fiscal 2002. The Company used $513,307 of cash to invest in property, plant, and equipment and $86,767 to pay down long-term debt. In addition, $197,727 of cash was used to repurchase 41,123 shares of the

Company's common stock in accordance with the stock buyback that was approved by the Criticare Board of Directors in the third quarter of fiscal 2002. The majority of these uses of cash were funded by $654,843 in proceeds received from the issuance of common stock related to the exercise and payment of 303,300 stock options in the last three quarters of fiscal 2002.

As noted above, the Company s Board of Directors authorized the repurchase of up to 500,000 shares of the Company s common stock in the third quarter of fiscal 2002. In accordance with this buyback, the Company purchased 35,100 shares in fiscal 2003, and has purchased 76,233 shares in total. At present, the Company does not expect to continue share repurchases in fiscal 2004, although a change in market conditions or other circumstances may cause the Company to make additional share repurchases. The Company expects that future share repurchases would be funded by cash generated from operations and current cash balances.

The Company believes all future capital and liquidity requirements will be satisfied by cash generated from operations, proceeds received from the issuance of common stock related to the exercise of stock options, and its current cash balances. The Company also has a $4,000,000 line of credit currently in place that could be utilized, if

necessary. At June 30, 2003 there were no borrowings outstanding under this line of credit. The Company violated a loan covenant under this line of credit related to achieving certain income levels. The bank waived compliance with this covenant subsequent to year end. This line expires in November 2003, but is expected to be extended with terms consistent with the current agreement.

The following table summarizes the Company s contractual cash obligations at June 30, 2003 in the categories set forth below, and the effect such obligations are expected to have on its liquidity and cash flow in future fiscal periods:

	2004	2005	2006	2007	Thereafter	Total
Operating leases	$ 323,266	$ 329,629	$ 315,448	$ 292,002	$ 48,892	$ 1,309,237
Other long-term obligations	15,912	15,912	14,586	7,956	197	54,563
Total contractual obligations	$ 339,178	$ 345,541	$ 330,034	$ 299,958	$ 49,089	$ 1,363,800

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.

Item 7A. 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 June 30, 2003, 2002, and 2001. 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.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

FINANCIAL STATEMENTS

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
JUNE 30, 2003 AND 2002

ASSETS	2003	2002
CURRENT ASSETS:		
Cash and cash equivalents (Note 1)	$ 3,716,446	$ 3,523,070
Accounts receivable, less allowance for doubtful accounts of $300,000, respectively (Note 1)	5,869,069	5,481,952
Investments (Notes 1 and 3)	--	2,304,689
Other receivables (Note 1)	311,276	502,348
Inventories (Notes 1 and 2)	6,347,208	7,134,803
Prepaid expenses	340,934	453,347
Total current assets	16,584,933	19,400,209
PROPERTY, PLANT AND EQUIPMENT (Notes 1 and 7):		
Land	--	925,000
Building	--	3,600,000
Machinery and equipment	2,264,697	2,007,322
Furniture and fixtures	919,077	809,277
Construction in progress	--	116,798
Leasehold improvements	212,229	--
Demonstration and loaner monitors	1,346,459	1,616,766
Production tooling	3,617,345	3,425,117
Property, plant and equipment cost	8,359,807	12,500,280
Less accumulated depreciation	6,266,399	6,517,220

Property, plant and equipment net	2,093,408	5,983,060
OTHER ASSETS (Notes 1 and 4):		
License rights and patents net	83,986	90,987
Total other assets	83,986	90,987
TOTAL ASSETS	$ 18,762,327	$ 25,474,256

See notes to consolidated financial statements.

LIABILITIES AND STOCKHOLDERS' EQUITY	2003	2002
CURRENT LIABILITIES:		
Accounts payable	$ 2,272,953	$ 2,331,496
Accrued liabilities:		
Compensation and commissions	850,034	770,578
Product warranties (Notes 1 and 5)	312,000	248,725
Other	254,470	490,922
Current maturities of long-term debt (Note 7)	--	93,589
Total current liabilities	3,689,457	3,935,310
LONG-TERM DEBT, less current maturities (Note 7)	--	3,103,536
OTHER LONG-TERM OBLIGATIONS	38,662	48,344
COMMITMENTS AND CONTINGENCIES (Notes 8, 13, and 14)		
TOTAL LIABILITIES	3,728,119	7,087,190
STOCKHOLDERS' EQUITY (Notes 1 and 9):		
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 and 11,199,524 shares issued, and 11,073,832 and 11,098,634 outstanding, respectively	448,161	447,981
Additional paid-in capital	23,360,244	23,350,124
Common stock held in treasury (130,192 and 100,890 shares, respectively)	(419,618)	(309,059)
Subscriptions receivable	(225,000)	(225,000)
Retained earnings (accumulated deficit)	(8,126,097)	(7,187,501)
Cumulative translation adjustment	(3,482)	5,832
Unrealized gain on investments	--	2,304,689

Total stockholders' equity	15,034,208	18,387,066
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 18,762,327	$ 25,474,256

See notes to consolidated financial statements.

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED JUNE 30, 2003, 2002 AND 2001

	2003	2002	2001
NET SALES (Note 11)	$ 28,562,943	$ 26,219,618	$ 27,736,304
COST OF GOODS SOLD	18,131,293	16,464,652	16,469,119
GROSS PROFIT	10,431,650	9,754,966	11,267,185
OPERATING EXPENSES:			
Sales and marketing (Note 1)	6,375,748	5,631,199	6,367,395
Research, development and engineering (Note 1)	2,736,877	2,339,696	2,446,907
Administrative (Note 8)	3,835,797	2,996,549	2,538,938
Total	12,948,422	10,967,444	11,353,240
LOSS FROM OPERATIONS	(2,516,772)	(1,212,478)	(86,055)
OTHER INCOME (EXPENSE):			
Interest expense (Note 7)	(91,533)	(246,207)	(253,150)
Interest income	51,197	76,771	157,782
Foreign currency exchange gain (loss) Note 1	82,403	(119,188)	--
Gain on sale of stock (Note 3)	1,290,252	--	--
Other income	245,857	75,921	3,191
Total	1,578,176	(212,703)	(92,177)
LOSS BEFORE INCOME TAXES	(938,596)	(1,425,181)	(178,232)
INCOME TAX PROVISION (Notes 1 and 6)	--	--	--
NET LOSS	$ (938,596)	$ (1,425,181)	$ (178,232)

NET LOSS PER COMMON SHARE (Note 1):			
Basic and diluted	$ (0.08)	$ (0.13)	$ (0.02)