

CRITICARE SYSTEMS INC /DE/
Form 10-K
September 28, 2004

**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)

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

For the fiscal year ended June 30, 2004

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 1-31943

Criticare Systems, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

39-1501563
(I.R.S. Employer Identification No.)

20925 Crossroads Circle, Suite 100, Waukesha, Wisconsin
(Address of Principal Executive Offices)

53186
(Zip Code)

Registrant's telephone number, including area code: 262-798-8282

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

| <u>Title of Each Class</u> | <u>Name of Each Exchange on Which Registered</u> |
|---|--|
| Voting Common Stock, \$.04 Par Value (together with associated Preferred Stock Purchase Rights) | American Stock Exchange |

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

None

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, 2003 (the last business day of the registrant's most recently completed second fiscal quarter) was \$37,562,335. Shares of voting common stock held as of December 31, 2003 by any person who was an executive officer or director of the Registrant as of December 31, 2003 and any person who beneficially owned 10% or more of the outstanding voting common stock as of December 31, 2003 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, 2004, there were 11,451,542 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 December 3, 2004 are incorporated by reference into Part III of this report.

[Cover page 2 of 2 pages.]

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. The Company expects to release a new generation VitalView telemetry system in the Fall of 2004 that will expand the monitoring capabilities of its central station from eight to sixteen patients.

Criticare is implementing two new business initiatives as part of its strategy to develop products for highly technical, growth oriented niche markets. The first of these initiatives involves monitoring products for anesthesia gases. In fiscal 2003, the Company introduced an anesthesia monitoring product line for sale both under the Criticare brand name and for sale to original equipment manufacturers ("OEMs"). The second initiative is the development of a highly specialized monitoring system for medical imaging applications. Criticare has entered into an agreement with an OEM to jointly develop and exclusively sell a highly specialized medical monitoring product to the OEM. In July 2004, Criticare shipped the initial prototypes of this monitoring product to this OEM.

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 10 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 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 CO₂ and CO₂/O₂ 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 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.

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Model 503DX 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 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 the manufacturer's 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

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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.

Marketing and Sales

Domestic Sales. At August 31, 2004, the Company's domestic sales force consisted of four employees and 104 independent dealers. The Company's sales force and independent dealers market the Company's vital signs monitors and pulse oximeters primarily to surgery centers, dental and physician offices, and nursing homes.

The Company sells some of its higher-end monitors (anesthetic agent monitors and VitalView central stations) to domestic hospitals. However, the Company does not have a significant presence in U.S. hospitals that generally purchase medical equipment through large group purchasing organizations (GPOs). These GPOs include large medical equipment suppliers who can provide not only medical monitors, but also the majority of the hospital's other medical equipment and service needs (such as CT scanners and MRI equipment).

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. In particular, sales of the Company's newly developed anesthesia products and a highly specialized monitoring system for medical imaging applications are expected to be mainly to new OEM partners. An OEM customer, Alaris Medical Systems, Inc., is the Company's largest customer and has generated 12.5%, 13.0%, and 13.4% of the Company's total revenue in fiscal 2004, 2003, and 2002, respectively. The recent acquisition of Alaris has resulted in an uncertainty as to the extent of the Company's future business with Alaris.

In fiscal 2004 the Company entered the domestic veterinary care market and has developed proprietary sensors, software and a portable wireless technology relevant to the monitoring of certain animal groups. The Company has also redesigned a number of its monitors for dedicated application to this market. A seasoned manager who has spent his entire career in the veterinary field was hired to direct the veterinary marketing and sales efforts.

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 2004, Criticare sold its products, principally to hospitals, in over 77 countries through over 94 independent dealers.

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In order to expand its business in China and Taiwan, in fiscal 2002 the Company changed its distributor in these countries. This distributor now manufactures, sells, and services Criticare labeled product in China and Taiwan.

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 2004, 41% of Criticare's net sales, or \$11.8 million, was attributable to international sales, of which approximately 61% was from sales in Europe and the Middle East, 12% was from sales to Pacific Rim countries and 27% was from sales to Canada and Central and South America. In fiscal 2003 and 2002, 41% and 39%, respectively, of Criticare's net sales were attributable to international sales. Other than inventory and accounts receivable for the Company's branch office 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, 2004, the Company had a customer service and technical support staff of 23 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 provides 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 generally 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 had 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 the U.S. and a portion of Criticare's production has been transitioned to China to continue to receive favorable pricing and a portion has been transitioned to the U.S. to satisfy the "made in U.S.A." requirements of certain customers. 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 manufacturing capabilities that the Taiwanese company has to produce product in Taiwan, China, and the U.S. 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, 2004, the Company had an in-house research, development and engineering staff of 23 people. The Company's research, development and engineering expenditures were \$2.5 million in fiscal 2004, \$2.7 million in fiscal 2003 and \$2.3 million in fiscal 2002.

Research and development efforts for the last three fiscal years have focused on the development and release of the 8500 series monitors which feature automatic identification and quantification of all five approved anesthetic agents and the development of a highly specialized monitoring system for medical imaging applications.

Competition

The markets for the Company's products are highly competitive. Many of Criticare's competitors, including the principal ones 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. In addition, internationally there are many in-country manufacturers that supply duty and tariff-free low cost monitors that make it difficult for the Company to be price competitive in these countries.

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, a subsidiary of General Electric, Andros, and Draeger Medical as the principal competitors. The market for vital signs monitors includes competitors such as General Electric, Siemens A.G., Philips, Welch Allyn, and Spacelabs Medical, Inc., a subsidiary of OSI Systems, Inc. that was acquired in March of 2004. Internationally, the market for vital signs monitors includes the competitors mentioned above, as well as in-country manufacturers that supply low cost monitors that are not required to comply with the rigorous regulations of the FDA.

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

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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 18 issued U.S. patents and one patent application pending. The Company's U.S. patents expire between 2005 and 2020. Criticare also has two issued foreign patents and 14 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," "POET IQ," "MPT," "REMOTEVUE," "MICROVIEW," "VITALVIEW," "SCHOLAR," and "WATERCHEK."

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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, 2004 Criticare had 87 employees in the U.S., including 23 in research, development and engineering, 23 in customer service and support, 12 in manufacturing and operations, 12 in administration, 11 in sales and marketing, and six in quality control. Criticare also utilizes three international country managers that work as independent contractors to support its international sales efforts. The Company also has an operation in India with 14 employees.

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, 2004 and 2003 was \$742,183 and \$407,695, 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.

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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 the Company.

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, 2004.

PART II**Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

The Company's common stock has traded on the American Stock Exchange under the symbol "CMD" since December 18, 2003. Prior to December 18, 2003, the Company's common stock was traded on the Nasdaq National Market under the symbol "CXIM." As of June 30, 2004, there were approximately 229 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, | | | |
|----------------|---------------------|--------|--------|--------|
| | 2004 | | 2003 | |
| Quarter Ended: | High | Low | High | Low |
| September 30 | \$3.85 | \$3.08 | \$3.99 | \$2.48 |
| December 31 | \$4.10 | \$3.07 | \$3.62 | \$2.41 |
| March 31 | \$4.45 | \$3.62 | \$3.77 | \$2.41 |
| June 30 | \$4.08 | \$2.85 | \$3.15 | \$2.24 |

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."

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| | 2004 | 2003 | 2002 | 2001 | 2000 |
|--|---------------|---------------|---------------|---------------|---------------|
| Net sales | \$ 28,591,481 | \$ 28,562,943 | \$ 26,219,618 | \$ 27,736,304 | \$ 27,154,236 |
| Net loss | (2,100,573) | (938,596) | (1,425,181) | (178,232) | (186,388) |
| Net loss per common share-- basic and diluted | \$ (0.19) | \$ (0.08) | \$ (0.13) | \$ (0.02) | \$ (0.02) |
| Average shares outstanding--basic and diluted | 11,240,685 | 11,071,735 | 10,876,818 | 10,171,394 | 8,694,918 |
| Stockholders' equity | \$ 13,789,300 | \$ 15,034,208 | \$ 18,387,067 | \$ 21,005,816 | \$ 18,798,952 |
| Long-term obligations | 344,128 | 38,662 | 3,151,879 | 3,270,131 | 3,552,474 |
| Working capital | 11,962,112 | 12,895,476 | 15,464,899 | 17,995,488 | 16,257,780 |
| Total assets | 19,542,341 | 18,762,327 | 25,474,256 | 29,871,854 | 27,210,867 |

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

Overview

Criticare designs, manufactures and markets vital signs and gas monitoring instruments and related noninvasive sensors used to monitor patients in many healthcare environments. The Company sells its products both in the U.S. and in international markets to customers such as hospitals, surgery centers, dental and physician offices, and nursing homes. In June 1999 the Company began to focus on selling to OEMs, and the OEM business has been a significant sales channel for the Company with 16.5% of total sales in fiscal 2004. The acquisition of Alaris Medical Systems, Inc., Criticare's largest OEM customer, has resulted in an uncertainty as to the extent of the Company's future business with Alaris.

Criticare is implementing two new business initiatives as part of its strategy to develop products for highly technical, growth oriented niche markets. The first of these initiatives involves monitoring products for anesthesia gases. In fiscal 2003, the Company introduced an anesthesia monitoring product line for sale both under the Criticare brand name and for sale to OEMs. The second initiative is the development of a highly specialized monitoring system for medical imaging applications. Criticare has entered into an agreement with an OEM to jointly develop and exclusively sell a highly specialized medical monitoring product to the OEM. In July 2004, Criticare shipped the initial prototypes of this monitoring product to this OEM.

The Company's results of operations in fiscal 2004 were adversely affected by its project with an International distributor. In fiscal 2003, Criticare formed a wholly owned subsidiary to supply medical equipment and supplies to medical facilities in countries in the Black Sea Economic Zone. The Company set up a standby letter of credit for \$400,000 on behalf of an International distributor in connection with this project. The standby letter of credit served as a guarantee for a \$450,000 line of credit that had been extended by a large Austrian bank to the International distributor to fund this project. Criticare also sold equipment to the International distributor, and the International

distributor has outstanding accounts receivable due to Criticare relating to this equipment. Due to adverse events relating to the International distributor subsequent to the end of fiscal 2004, Criticare believes that the project will not generate sufficient cash flow to fund the International distributor's line of credit, which will lead to the standby letter of credit being called, and that Criticare will likely be unable to collect the receivable due from the International

distributor or to recover the equipment shipped to the International distributor. As a result, Criticare has recognized a charge to other expenses in the amount of \$400,000 to reserve for the impending call of the letter of credit and has set up an allowance for the expected write off of the receivable in the amount of \$421,000. A reserve in the amount of \$90,000 has also been established to satisfy a claim for duties and Value Added Tax associated with importation of products into a foreign country on behalf of the International distributor.

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 | | |
|---------------------------------------|--------------------------------|-------------|-------------|
| | <u>Years Ended June 30,</u> | | |
| | 2004 | 2003 | 2002 |
| Net sales | 100.0% | 100.0% | 100.0% |
| Cost of goods sold | 58.8 | 63.5 | 62.8 |
| Gross profit | 41.2 | 36.5 | 37.2 |
| Operating expenses: | | | |
| Sales and marketing | 25.0 | 22.3 | 21.5 |
| Research, development and engineering | 8.9 | 9.6 | 8.9 |
| Administrative | 12.8 | 13.4 | 11.4 |
| Total | 46.7 | 45.3 | 41.8 |
| Loss from operations | (5.5) | (8.8) | (4.6) |
| Interest expense | 0.0 | (0.3) | (0.9) |
| Interest income | 0.1 | 0.2 | 0.3 |
| Foreign currency exchange gain (loss) | 0.0 | 0.3 | (0.5) |
| Gain on sale of stock | 0.0 | 4.5 | -- |
| Other income | (1.9) | 0.9 | 0.3 |
| Loss before income taxes | (7.3) | (3.2) | (5.4) |
| Income tax provision | -- | -- | -- |
| Net loss | (7.3)% | (3.2)% | (5.4)% |

Fiscal Year Ended June 30, 2004 Compared to June 30, 2003

Net sales of \$28,591,481 for the fiscal year ended June 30, 2004 compared to \$28,562,943 of net sales generated in fiscal 2003. An 11.9% increase in the number of units shipped was partially offset by a 10.3% reduction in the average sales price per unit and a 6.9% decrease in accessory sales in the current year. The higher unit sales and lower average sales price per unit were driven by a large shipment of pulse oximeters to supply a government tender in Mexico. These units monitor pulse oximetry only and therefore carry a much lower average selling price than the Company's equipment that monitors multiple vital signs parameters. OEM sales in fiscal 2004 were \$4,631,000 and represented

16.5% of total sales, compared to \$5,457,000 (19.1% of total sales) in fiscal 2003.

The gross profit percentage of 41.2% realized in fiscal 2004 increased from the 36.5 % generated in the prior year. The lower margins in the prior year were driven mainly by \$1,752,352 in charges to cost of goods sold to increase the obsolescence reserve for inventory associated with discontinued products and for potential obsolete inventory. Charges to cost of goods sold for potentially obsolete inventory totaled \$535,024 in the current year and this \$1,217,328 reduction in charges in the current year increased margins from the prior year.

Total operating expenses in fiscal 2004 increased by \$395,790 from the prior year as a \$174,581 reduction in administrative expenses and a \$204,748 decrease in research, development and engineering expenses partially offset a \$775,119 increase in sales and marketing expenses. A \$364,240 reduction in legal and consulting fees primarily related to the internal review conducted in the prior year by the Company of its import and export procedures was the main contributor to the lower administrative expenses. In addition, a final payment in the prior year of \$150,000 made to the Company's former CEO and founder to satisfy past severance obligation issues increased administrative expenses in the prior year compared to the current year. These reductions were partially offset by the increase in bad debt expense of \$331,240 related to the reserve of the receivable due from the International distributor. The lower research, development and engineering expenses were mainly due to funding received from an OEM business partner to jointly develop a highly specialized monitoring system for medical imaging applications that was partially offset by higher spending to support the project. The higher sales and marketing expenses were mainly driven by increased spending to promote the Company's new line of anesthesia monitoring products and to enter the veterinary market, including the hiring of four direct salespeople to support these efforts. Also contributing to the increase in sales and marketing spending were clinical trials conducted to test enhancements made to one of the Company's vital signs parameters.

The Company generated other expense of \$526,060 in fiscal 2004 compared to other income of \$1,578,176 that was recognized in the prior year. Other income in the prior year included the recognition of a \$1,290,252 gain on the sale of the Company's Immtech International, Inc. stock, \$93,000 in profits from the completion of a medical equipment integration project with an International distributor, an \$82,403 foreign currency exchange gain related to the Company's operation in India, and a \$41,208 gain on the sale of the Company's building. Total other expense in the current year includes a \$200,000 charge to settle a dispute with a customer over a 1999 product installation to avoid litigation. The Company elected to settle this issue rather than incur the significant legal and administrative costs deemed necessary to successfully defend its position. Total other expenses include a \$400,000 charge for the potential call of a standby letter of credit used to guarantee borrowings by the International distributor. Total other expenses also include a \$90,000 charge to satisfy a claim for duties and Value Added Tax associated with importation of products into a foreign country on behalf of the International distributor.

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 net sales generated in fiscal 2002. A 12.5% increase in international sales and a 6.6% increase in domestic sales drove revenue higher in fiscal 2003. 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 in fiscal 2003 as compared to fiscal 2002. 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 fiscal 2002. 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 the end of fiscal 2003. 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 fiscal 2002.

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 of fiscal 2003 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 the fourth quarter of fiscal 2003, increasing the risk of obsolescence of component parts maintained for its old line of anesthesia monitoring products. Mainly due to these two events that

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arose in the fourth quarter of fiscal 2003, the Company increased its reserve for obsolete inventory to \$1.4 million from its \$464,000 balance at the end of the third quarter of fiscal 2003. This increase in the obsolescence reserve in the fourth quarter of fiscal 2003 reduced gross margins to 24.1% and increased the loss for the fourth quarter of fiscal 2003 to \$1,286,799.

Total operating expenses in fiscal 2003 were almost \$2.0 million higher than fiscal 2002 and more than offset the favorable impact of higher sales in fiscal 2003. Administrative expenses increased by \$839,248 in fiscal 2003 as compared to fiscal 2002 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 fiscal 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 fiscal 2002 due mostly to a \$330,000 increase in employee and dealer commissions in fiscal 2003 as compared to fiscal 2002 driven by the higher sales and an increase in bad debt expense of \$221,000 in fiscal 2003 as compared to fiscal 2002. 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 fiscal 2003.

Research, development, and engineering expenses were up \$397,181 in fiscal 2003 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 fiscal 2002 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 fiscal 2002. 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 with an International distributor, 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 fiscal 2003 related to the Company's operation in India compared to a \$119,188 foreign currency exchange loss recognized in fiscal 2002. 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 in fiscal 2003 as compared to fiscal 2002 and, consequently, contributed to higher other income in fiscal 2003 over 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 there was no activity in fiscal 2004 for these integration services and the activity for fiscal 2003 was not material, they are included in the accompanying statements of operations for fiscal 2003 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 2004, the reserve for obsolete inventory was decreased \$790,000 to \$610,000 at June 30, 2004 due mainly to the disposal of obsolete inventory that had been reserved for in prior years. 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.

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.

Liquidity and Capital Resources

As of June 30, 2004, the Company had a cash balance of \$3,738,825 that was basically level with its fiscal 2003 year-end cash balance of \$3,716,446. The Company has continued to maintain a bank debt free balance sheet since August of 2002 when it sold its building and used the proceeds from the sale to retire the bank debt on the facility.

The Company has been able to increase its cash position \$376,721 over the last three fiscal years despite generating losses of \$4,464,350 during this period. Non-cash expenses consisting primarily of depreciation expense and provisions for obsolete inventory decreased the Company's profitability \$5,264,669 during the last three fiscal years, but did not impact the Company's cash flows. Over the last three fiscal years the Company has been able to fund \$934,562 of cash used in operations and capital spending of \$1,702,745 primarily with \$1,531,607 of cash provided from the exercise of stock options and \$1,290,252 from the sale in fiscal 2003 of the Company's shares of Immtech International, Inc. stock.

In fiscal 2004, \$855,664 of cash provided from the exercise of 470,725 shares under expiring stock options more than offset \$413,063 of capital spending and \$408,864 of cash used in operations. In fiscal 2003, the Company generated cash of \$1,290,252 through the sale of its shares of Immtech International, Inc. stock and another \$598,039 of net cash through the sale of its building and the retirement of the debt on the facility. These cash inflows more than offset the \$808,967 of cash used in operations and \$776,375 of capital spending in fiscal 2003.

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. No major capital equipment expenditures are expected in the Company's next fiscal year ending June 30, 2005. The Company also has a \$1,000,000 line of credit currently in place that could be utilized, if necessary. At June 30, 2004, there were no borrowings outstanding under this line of credit. The Company violated loan covenants under this line of credit related to achieving minimum levels of tangible net worth and income. The bank waived compliance with these covenants subsequent to year end. This line expires in November 2004, 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, 2004 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:

| | 2005 | 2006 | 2007 | 2008 | Thereafter | Total |
|------------------------------------|--------------|------------|------------|------------|------------|--------------|
| Operating leases | \$ 332,662 | \$ 329,776 | \$ 321,206 | \$ 73,258 | \$ 22,678 | \$ 1,079,580 |
| Capital leases | 82,560 | 82,560 | 82,560 | 82,560 | 62,640 | 392,880 |
| Contract manufacturing obligations | 1,110,000 | -- | -- | -- | -- | 1,110,000 |
| Other long-term obligations | 14,352 | 13,605 | 7,176 | 865 | -- | 35,998 |
| Total contractual obligations | \$ 1,539,574 | \$ 425,941 | \$ 410,942 | \$ 156,683 | \$ 85,318 | \$ 2,618,458 |

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, 2004, 2003, and 2002. 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 for the fiscal year ended June 30, 2004. 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

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**CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
JUNE 30, 2004 AND 2003**

| ASSETS (Note 6) | 2004 | 2003 |
|---|--------------|--------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents (Notes 1 and 10) | \$ 3,738,825 | \$ 3,716,446 |
| Accounts receivable, less allowance for doubtful accounts of \$260,000 and \$300,000, respectively (Note 1) | 6,489,884 | 5,627,198 |
| Other receivables (Note 1) | 359,806 | 553,147 |
| Inventories (Notes 1 and 2) | 6,418,135 | 6,347,208 |
| Prepaid expenses | 364,375 | 340,934 |
| Total current assets | 17,371,025 | 16,584,933 |
| PROPERTY, PLANT AND EQUIPMENT (Note 1): | | |
| Machinery and equipment | 2,675,093 | 2,264,697 |
| Furniture and fixtures | 937,906 | 919,077 |
| Leasehold improvements | 218,423 | 212,229 |
| Demonstration and loaner monitors | 945,339 | 1,346,459 |
| Production tooling | 2,030,618 | 3,617,345 |
| Property, plant and equipment - cost | 6,807,379 | 8,359,807 |
| Less accumulated depreciation | 4,713,049 | 6,266,399 |
| Property, plant and equipment - net | 2,094,330 | 2,093,408 |

| | | | |
|----------------------------------|-----------|-------------------|----------------------|
| OTHER ASSETS (Notes 1 and 3): | | | |
| License rights and patents - net | | 76,985 | 83,986 |
| Total other assets | | 76,985 | 83,986 |
| TOTAL ASSETS | \$ | 19,542,341 | \$ 18,762,327 |

See notes to consolidated financial statements.

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| LIABILITIES AND STOCKHOLDERS' EQUITY | 2004 | 2003 |
|---|----------------------|----------------------|
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 3,237,406 | \$ 2,272,953 |
| Accrued liabilities: | | |
| Compensation and commissions | 863,113 | 850,034 |
| Product warranties (Notes 1 and 4) | 444,000 | 312,000 |
| Liability under guarantees (Note 13) | 490,000 | -- |
| Out of court settlement (Note 7) | 200,000 | -- |
| Obligations under capital lease (Note 12) | 57,712 | -- |
| Other | 174,395 | 254,470 |
| Total current liabilities | 5,466,626 | 3,689,457 |
| LONG-TERM LIABILITIES: | | |
| Obligations under capital lease (Note 12) | 264,770 | -- |
| Other long-term obligations | 21,646 | 38,662 |
| Total long-term liabilities | 286,416 | 38,662 |
| COMMITMENTS AND CONTINGENCIES (Notes 7, 9, 12 and 13) | | |
| TOTAL LIABILITIES | 5,753,042 | 3,728,119 |
| STOCKHOLDERS' EQUITY (Notes 1 and 8): | | |
| Preferred stock - \$.04 par value, 500,000 shares authorized, no shares issued or outstanding | -- | -- |
| Common stock - \$.04 par value, 15,000,000 shares authorized, 11,574,749 and 11,204,024 shares issued, and 11,450,021 and 11,073,832 outstanding, respectively | 462,990 | 448,161 |
| Additional paid-in capital | 23,965,900 | 23,360,244 |
| Common stock held in treasury (124,728 and 130,192 shares, respectively) | (409,439) | (419,618) |
| Subscriptions receivable | -- | (225,000) |
| Retained earnings (accumulated deficit) | (10,226,670) | (8,126,097) |
| Cumulative translation adjustment | (3,482) | (3,482) |
| Total stockholders' equity | 13,789,299 | 15,034,208 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 19,542,341 | \$ 18,762,327 |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED JUNE 30, 2004, 2003 AND 2002

| | 2004 | 2003 | 2002 |
|---|----------------|---------------|----------------|
| NET SALES (Notes 10 and 11) | \$ 28,591,481 | \$ 28,562,943 | \$ 26,219,618 |
| COST OF GOODS SOLD | 16,821,782 | 18,131,293 | 16,464,652 |
| GROSS PROFIT | 11,769,699 | 10,431,650 | 9,754,966 |
| OPERATING EXPENSES: | | | |
| Sales and marketing (Note 1) | 7,150,867 | 6,375,748 | 5,631,199 |
| Research, development and engineering (Note 1) | 2,532,129 | 2,736,877 | 2,339,696 |
| Administrative (Note 9) | 3,661,216 | 3,835,797 | 2,996,549 |
| Total | 13,344,212 | 12,948,422 | 10,967,444 |
| LOSS FROM OPERATIONS | (1,574,513) | (2,516,772) | (1,212,478) |
| OTHER (EXPENSE) INCOME: | | | |
| Interest expense (Note 12) | (9,282) | (91,533) | (246,207) |
| Interest income | 37,176 | 51,197 | 76,771 |
| Foreign currency exchange gain (loss) - Note 1 | -- | 82,403 | (119,188) |
| Gain on sale of stock (Note 1) | -- | 1,290,252 | -- |
| Other (expense) income | (553,954) | 245,857 | 75,921 |
| Total | (526,060) | 1,578,176 | (212,703) |
| LOSS BEFORE INCOME TAXES | (2,100,573) | (938,596) | (1,425,181) |
| INCOME TAX PROVISION (Notes 1 and 5) | -- | -- | -- |
| NET LOSS | \$ (2,100,573) | \$ (938,596) | \$ (1,425,181) |
| NET LOSS PER COMMON SHARE (Note 1): | | | |
| Basic and diluted | \$ (0.19) | \$ (0.08) | \$ (0.13) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING (Note 1): | | | |
| Basic and diluted | 11,240,685 | 11,071,735 | 10,876,818 |

See notes to consolidated financial statements.

**CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED JUNE 30, 2004, 2003 AND 2002**

| | Common Stock | Additional Paid-In | Common Stock Treasury | Subscriptions | Retained Earning Accumulated |
|-------------------------------|--------------|-------------------------------|--------------------------|---------------|------------------------------------|
| | | Cumulative Translation | | | |
| | | Unrealized Gain on Investment | | | |
| | | Total Stockholders | | | |
| | | Shares | | | |
| | | Amount | | | |
| | | Capital | | | |
| | | Shares | | | |
| | | Cost | | | |
| | | Receivable | | | |
| | | (Deficit) | | | |
| | | Adjustment | | | |
| | | Investment | | | |
| | | Equity | | | |
| Balance, June 30, 2001 | | | | | 10,796,224 |
| \$ | | | | | 431,849 |

| | | |
|-----------------------------------|--|------------|
| \$ | | 22,494,548 |
| | | 64,134 |
| \$ | | (119,467 |
|) | | |
| \$ | | 0 |
| \$ | | (5,771,568 |
|) | | |
| \$ | | 0 |
| \$ | | 3,970,454 |
| \$ | | 21,005,816 |
| Net loss | | |
| | | (1,425,181 |
|) | | |
| | | (1,425,181 |
|) | | |
| Unrealized (loss) on investment | | |
| | | (1,665,765 |
|) | | |
| | | (1,665,765 |
|) | | |
| Cumulative translation adjustment | | |
| | | 9,248 |
| | | 5,832 |
| | | 15,080 |
| Comprehensive income/(loss) | | |
| | | (3,075,866 |
|) | | |
| Exercise of options | | |

| | |
|--|------------|
| | 403,300 |
| | 16,132 |
| | 848,121 |
|) | (225,000 |
| | 639,253 |
| Employee common stock purchased from treasury | |
| | 7,455 |
|) | (4,367 |
| | 8,135 |
| | 15,590 |
| Repurchase of Company stock | |
| | 41,123 |
|) | (197,727 |
| | (197,727 |
|) | |
| Balance, June 30, 2002 | |
| | 11,199,524 |
| | 447,981 |
| | 23,350,124 |
| | 100,890 |
|) | (309,059 |
|) | (225,000 |
|) | (7,187,501 |

| | |
|---|-------------|
| | 5,832 |
| | 2,304,689 |
| | 18,387,066 |
| Net loss | |
|) | (938,596) |
|) | (938,596) |
| Unrealized holding (loss) arising during period | |
|) | (1,014,437) |
|) | (1,014,437) |
| Reclassification (gain) included in net income | |
|) | (1,290,252) |
|) | (1,290,252) |
| Cumulative translation adjustment | |
|) | (9,314) |
|) | (9,314) |
| Comprehensive income/(loss) | |
|) | (3,252,599) |
| Exercise of options | |
| | 4,500 |
| | 180 |
| | 7,133 |
| | 7,313 |

| | |
|--|-------------|
| Employee common stock purchased from treasury | 2,987 |
|) | (5,798) |
| | 10,800 |
| | 13,787 |
| Repurchase of Company stock | 35,100 |
|) | (121,359) |
|) | (121,359) |
| Balance, June 30, 2003 | |
| | 11,204,024 |
| | 448,161 |
| | 23,360,244 |
| | 130,192 |
|) | (419,618) |
|) | (225,000) |
|) | (8,126,097) |
|) | (3,482) |
| | 0 |
| | 15,034,208 |
| Net loss | (2,100,573) |

| | |
|--|------------|
|) | |
|) | (2,100,573 |
| Comprehensive income/(loss) | |
|) | (2,100,573 |
| Exercise of options | |
| | 370,725 |
| | 14,829 |
| | 600,455 |
| | 225,000 |
| | 840,284 |
| Employee common stock purchased from treasury | |
| | 5,201 |
|) | (5,464 |
| | 10,179 |
| | 15,380 |
| Balance, June 30, 2004 | |
| | 11,574,749 |
| \$ | 462,990 |
| \$ | 23,965,900 |
| | 124,728 |
| \$ | (409,439 |
|) | |
| \$ | 0 |
| \$ | |

| | |
|----|--------------|
|) | (10,226,670) |
| \$ | |
|) | (3,482) |
| \$ | |
|) | 0 |
| \$ | |
| | 13,789,300 |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED JUNE 30, 2004, 2003 AND 2002

| | 2004 | 2003 | 2002 |
|--|----------------|--------------|----------------|
| OPERATING ACTIVITIES: | | | |
| Net loss | \$ (2,100,573) | \$ (938,596) | \$ (1,425,181) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | | |
| Depreciation | 635,322 | 881,703 | 865,291 |
| Amortization | 7,001 | 7,001 | 7,002 |
| Gain on sale of fixed assets | -- | (41,208) | (5,292) |
| Provision for doubtful accounts | 393,758 | 38,566 | (700,000) |
| Provision for obsolete inventory | 509,001 | 1,752,352 | 621,000 |
| Gain on sale of Immtech stock | -- | (1,290,252) | -- |
| Changes in assets and liabilities: | | | |
| Accounts receivable | (1,256,444) | (425,683) | 2,340,512 |
| Other receivables | 193,341 | 191,072 | (468,560) |
| Inventories | (469,269) | (934,389) | 691,753 |
| Prepaid expenses | (23,441) | 112,413 | 48,825 |
| Accounts payable | 964,452 | (58,543) | (1,090,280) |
| Accrued liabilities | 737,988 | (103,403) | (601,801) |
| Net cash (used in) provided by operating activities | (408,864) | (808,967) | 283,269 |
| INVESTING ACTIVITIES: | | | |
| Purchases of property, plant and equipment, net | (413,063) | (776,375) | (513,307) |
| Proceeds from sale of fixed assets | -- | 3,795,164 | 5,575 |
| Proceeds from sale of Immtech stock | -- | 1,290,252 | -- |

| | | | |
|---|--------------|--------------|--------------|
| Net cash (used in) provided by investing activities | (413,063) | 4,309,041 | (507,732) |
| FINANCING ACTIVITIES: | | | |
| Repurchase of Company common stock | -- | (121,359) | (197,727) |
| Retirement of long-term debt | -- | (3,197,125) | (86,767) |
| Retirement of obligation under capital lease | (11,358) | -- | -- |
| Proceeds from issuance of common stock | 855,664 | 21,100 | 654,843 |
| Net cash provided by (used in) financing activities | 844,306 | (3,297,384) | 370,349 |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH | | | |
| | -- | (9,314) | 15,080 |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | | | |
| | 22,379 | 193,376 | 160,966 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR | | | |
| | 3,716,446 | 3,523,070 | 3,362,104 |
| CASH AND CASH EQUIVALENTS, END OF YEAR | | | |
| | \$ 3,738,825 | \$ 3,716,446 | \$ 3,523,070 |

SUPPLEMENTAL CASH FLOW INFORMATION:

Cash paid for:

| | | | |
|--|-----------|-------------|-------------|
| Income taxes paid-net | \$ 7,498 | \$ 16,288 | \$ 12,309 |
| Interest | 11,535 | 110,322 | 246,749 |
| Noncash investing and financing activities: | | | |
| Cost of fixed asset disposals | 1,898,210 | 3,754,245 | 168,320 |
| Property, plant and equipment acquired under capital lease | 333,840 | -- | -- |
| Holding (loss) on investment in Immtech | -- | (1,014,437) | (1,665,765) |

See notes to consolidated financial statements.

NOTES TO FINANCIAL STATEMENTS

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED JUNE 30, 2004, 2003 AND 2002

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business -- Criticare Systems, Inc. designs, manufactures and markets patient monitoring equipment and related accessories to the health care community worldwide and is headquartered in Waukesha, Wisconsin. The Company sells domestically primarily to oral and stand-alone general surgery centers and hospitals through regional sales managers and a dealer network. Internationally, the Company sells mainly to hospitals through country managers and a worldwide dealer network. In addition, the Company sells modules and stand-alone monitors worldwide to original equipment manufacturers ("OEMs").

Principles of Consolidation -- The consolidated financial statements include the accounts of Criticare Systems, Inc. (the "Company") and its wholly owned subsidiaries: Criticare International GmbH Marketing Services ("Criticare International"), CSI Trading, Inc. ("CSI Trading"), Criticare Service GmbH, Criticare Biomedical, Inc. ("Criticare Biomedical"), Sleep Care, Inc. ("Sleep Care"), and Criticare Integration, Inc. ("Criticare Integration"). CSI Trading was incorporated in November 1996 to assist with European marketing activities and includes an operation in India. All significant intercompany accounts and transactions have been eliminated.

Cash Equivalents -- The Company considers all investments with purchased maturities of less than three months to be cash equivalents.

Accounts Receivable and Allowance for Doubtful Accounts -- Accounts receivable are customer obligations due under normal trade terms. The Company sells its products to distributors, original equipment manufacturers, and end users in medical facilities such as hospitals, surgery centers, nursing homes, and physician offices. The Company performs continuing credit evaluations of its customers' financial condition and although it generally does not require collateral, letters of credit may be required from customers in certain circumstances.

Management reviews accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. The Company includes any accounts receivable balances that are determined to be uncollectible, along with a general reserve, in its overall allowance for doubtful accounts. After all attempts to collect a receivable have failed, the receivable is written off against the allowance. Based on

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the information available, the Company believes its allowance for doubtful accounts as of June 30, 2004 and 2003 is adequate. However, actual write-offs might exceed the recorded allowance.

Inventories -- Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out method.

Investments -- In accordance with Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," debt and equity securities not classified as either held-to-maturity securities or trading securities are classified as available-for-sale securities and reported at fair value, with unrealized gains and losses excluded from earnings and reported in a separate component of shareholders' equity. The Company's investments were in marketable equity securities and were classified as available-for-sale securities. The Company's investment in stock of Immtech International, Inc. was sold at a gain in 2003. There were no held-to-maturity or trading securities as of June 30, 2004.

Other Receivables -- Other receivables in fiscal 2004 and 2003 consist mainly of tender deposits in the amount of \$122,218 and \$104,798, respectively, and receivables to be paid via letters of credit amounting to \$81,862 and \$85,395, respectively. In addition, in fiscal 2003 other receivables included a trade receivable of \$232,205, which was assumed by a new distributor in China. This receivable was paid in full during fiscal 2004.

Property, Plant and Equipment -- Property, plant and equipment is recorded at cost. Each member of the Company's sales force is provided with demonstration monitors to assist them in their sales efforts. The Company also has loaner monitors which are used to temporarily replace a customer's unit when it is being repaired or upgraded. Depreciation is provided over the estimated useful lives of the assets. The building, which was sold in August 2002, was being depreciated over 40 years prior to the sale. The estimated useful lives of other property and equipment are

as follows:

| <u>Classification</u> | <u>Estimated Useful Lives</u> |
|-----------------------------------|-------------------------------|
| Machinery and equipment | 5-7 years |
| Furniture and fixtures | 5 years |
| Leasehold improvements | 4-5 years |
| Demonstration and loaner monitors | 4 years |
| Production tooling | 5-7 years |

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The Company periodically assesses the recoverability of long-lived assets, including property and equipment and intangibles, in accordance with the Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of" ("SFAS No. 144"), when indications of potential impairment exist. The amount of any impairment is calculated by comparing the estimated fair market value with the carrying value of the related asset. Management considers such factors as current operating results, trends, and future prospects, in addition to other economic factors in performing this analysis. No such impairments exist at June 30, 2004 and 2003.

License Rights and Patents -- The Company adopted SFAS 142, "Goodwill and Other Intangible Assets," during the period ended June 30, 2003 to account for its license rights and patents. License rights and patents are carried at cost and are amortized using the straight-line method over their estimated useful life as follows:

| <u>Classification</u> | <u>Estimated Useful Lives</u> |
|----------------------------|-------------------------------|
| License rights and patents | 17 years |

License rights and patents are evaluated for impairment when events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable through the estimated undiscounted future cash flows resulting from the use of these assets. When any such impairment exists, the related assets will be written down to fair value.

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.

Shipping Costs -- Any shipping costs that are billable to the customer are included in revenue and all shipping costs are included in cost of goods sold in the accompanying consolidated statements of operations.

Product Warranties -- Estimated costs for product warranties are accrued for and charged to operations as the related products are shipped and installed.

Marketing Expenses -- Marketing expenses include all of the Company's sales related costs. In fiscal 2002 recoveries of bad debts expensed in prior years more than offset additional provisions expensed in the current year, resulting in a net credit of bad debt expense of \$(183,046). Bad debt expense totaled \$393,758 and \$38,566 in fiscal 2004 and 2003,

respectively.

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Advertising Costs -- Advertising costs are expensed as incurred. Advertising costs totaled \$101,174, \$76,950, and \$62,465 for the years ended June 30, 2004, 2003, and 2002, respectively.

Research and Development Expenses -- Research and development costs are charged to operations as incurred. Such expenses approximated \$2,271,000, \$2,503,000 and \$2,147,000 in fiscal 2004, 2003, and 2002, respectively.

Income Taxes -- The Company accounts for income taxes using an asset and liability approach. Deferred income tax assets and liabilities are computed annually for differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. The Company pays income taxes in certain states that require an annual minimum tax. These taxes are included in administrative expenses in the consolidated statements of operations.

Translation of Foreign Currency -- The Company follows the translation policy as provided by Financial Accounting Standards No. 52, "Foreign Currency Translation" in translating the financial statements of its operation in India from Indian rupees to U.S. dollars. Accordingly, assets and liabilities are translated at the rate of exchange at the balance sheet date. Income and expense items are translated at the average exchange rate prevailing throughout the year. Due to the fact that the variance between the U.S. dollar and the Indian rupee was not material, Criticare elected to use the same exchange rate in fiscal 2004 as in fiscal 2003.

Net Loss Per Common Share -- Basic loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted income per share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. The basic and diluted weighted average number of common shares outstanding in the financial statements are the same in fiscal years 2004, 2003, and 2002 because including a diluted calculation in a loss position would produce an anti-dilutive per share amount. The number of diluted weighted average common shares outstanding would be higher by 335,215 shares in 2004, 328,172 shares in 2003, and 597,129 shares in 2002 without this anti-dilutive impact.

Stock Options -- The Company grants options to purchase Criticare Systems, Inc. common shares under stock option plans that are described more fully in Note 8. The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," and the additional disclosures required by SFAS No. 148, "Accounting for Stock Based Compensation - Transition and Disclosure," but applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for its stock option plans. If the

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Company had elected to recognize compensation cost for the options granted during the years ended June 30, 2004, 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:

| | Years Ended June 30, | | |
|--|----------------------|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Net loss--as reported | \$ (2,100,573) | \$ (938,596) | \$ (1,425,181) |
| Less compensation expense for options granted | 285,566 | 173,152 | 131,171 |
| Net loss--pro forma | \$ (2,386,139) | \$ (1,111,748) | \$ (1,556,352) |
| Net loss per common share--as reported | \$ (0.19) | \$ (0.08) | \$ (0.13) |
| Less compensation expense for options granted | 0.02 | 0.02 | 0.01 |
| Net loss per common share--pro forma (basic and diluted) | \$ (0.21) | \$ (0.10) | \$ (0.14) |

Fair Value of Financial Instruments -- The Company's financial instruments under SFAS No. 107 "Disclosure About Fair Value of Financial Instruments," includes cash, accounts receivable, accounts payable, borrowings under line of credit facility and long-term debt. The Company believes that the carrying amounts of these accounts are a reasonable estimate of their fair value because of the short-term nature of such instruments or, in the case of long-term debt because of interest rates available to the Company for similar obligations.

Comprehensive Income -- In 1999, the Company adopted SFAS No. 130, "Reporting Comprehensive Income." This statement establishes rules for the reporting of comprehensive income and its components. Comprehensive income consists of net income, foreign currency translation adjustments and unrealized gains on investments, and is presented in the consolidated statements of stockholders' equity.

Use of Estimates -- The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reclassifications -- Certain amounts from the fiscal 2003 financial statements have been reclassified to conform to the fiscal 2004 presentation.

2. INVENTORIES

Inventories consist of the following as of June 30:

| | 2004 | 2003 |
|--------------------------------|--------------|--------------|
| Component parts | \$ 1,988,415 | \$ 2,762,803 |
| Work in process | 781,156 | 811,906 |
| Finished units | 4,258,565 | 4,172,499 |
| Total inventories | 7,028,136 | 7,747,208 |
| Less: reserve for obsolescence | 610,000 | 1,400,000 |
| Net inventory | \$ 6,418,135 | \$ 6,347,208 |

3. LICENSE RIGHTS AND PATENTS

The components of and changes in the carrying amount of license rights and patents are as follows:

| | 2004 | 2003 |
|--------------------------------|-------------|-------------|
| License rights and patents | \$ 196,777 | \$ 196,777 |
| Accumulated amortization | (119,792) | (112,791) |
| Net license rights and patents | \$ 76,985 | \$ 83,986 |

Future amortization of license and patents is as follows at June 30, 2004:

| Year ended June 30, | |
|---------------------|---------------|
| 2005 | \$ 7,001 |
| 2006 | 7,001 |
| 2007 | 7,001 |
| 2008 | 7,001 |
| 2009 | 7,001 |
| Thereafter | <u>41,980</u> |
| Total | \$76,985 |

Approximately \$7,000 of amortization was charged to operations in each of the fiscal years ended June 30, 2004, 2003, and 2002.

4. PRODUCT WARRANTY

The Company's products are subject to warranties, and therefore liabilities are established for the estimated future costs of repair or replacement and included in cost of sales at the time the related sale is recognized. These liabilities are adjusted based on management's best estimates of future warranty costs after considering historical and projected product failure rates and product repair costs. In the event that actual experience differs from these best estimates, changes in the Company's warranty liabilities might become necessary.

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Changes in the Company's warranty liability for fiscal years 2004 and 2003 are as follows:

| | 2004 | 2003 |
|--|-------------|-------------|
| Balance, beginning of year | \$ 312,000 | 248,725 |
| Warranties issued | 453,212 | 495,885 |
| Settlements | (321,212) | (352,865) |
| Changes in estimated pre-existing warranties | -- | (79,745) |
| Balance, end of year | \$ 444,000 | \$ 312,000 |

5. INCOME TAXES

The Company accounts for income taxes using an asset and liability approach which generally requires the recognition of deferred income tax assets and liabilities based upon the expected future income tax consequences of events that have previously been recognized in the Company's financial statements or tax returns. In addition, a valuation allowance is recognized if it is more likely than not that some or all of the deferred income tax asset will not be realized. A valuation allowance is used to offset the related net deferred income tax assets due to uncertainties of realizing the benefits of certain net operating loss and tax credit carryforwards.

The valuation allowance was increased \$1,095,000 in 2004 and \$1,263,000 in 2003.

Significant components of the Company's deferred income tax assets and deferred income tax liabilities are as follows:

| | June 30, 2004 | June 30, 2003 | June 30, 2002 |
|---|------------------|------------------|------------------|
| Deferred income tax assets: | | | |
| Accounts receivable and sales allowances | \$ 133,000 | \$ 148,000 | \$ 146,000 |
| Inventory allowances | 269,000 | 580,000 | 400,000 |
| Product warranties | 174,000 | 122,000 | 98,000 |
| Other accrued liabilities | 135,000 | 122,000 | 136,000 |
| Severance pay accrual | 14,000 | 21,000 | 24,000 |
| Federal net operating loss carryforwards | 5,772,000 | 4,543,000 | 4,282,000 |
| State net operating loss carryforwards | 574,000 | 502,000 | 536,000 |
| Federal tax credit carryforwards | 198,000 | 198,000 | 152,000 |
| Investment losses not deducted | 118,000 | 118,000 | 709,000 |
| Total deferred income tax assets | 7,387,000 | 6,354,000 | 6,483,000 |
| Deferred income tax liabilities: | | | |
| Excess of tax over book depreciation and amortization | (22,000) | (106,000) | (585,000) |
| Prepaid expenses | (54,000) | (32,000) | (41,000) |
| Unrealized gain on investments | 0 | 0 | (904,000) |
| Total deferred income tax liabilities | (76,000) | (138,000) | (1,530,000) |
| Valuation allowance | (7,311,000) | (6,216,000) | (4,953,000) |
| Net deferred income taxes recognized in the consolidated balance sheets | \$ 0 | \$ 0 | \$ 0 |

At June 30, 2004, the Company had federal net operating loss carryforwards of approximately \$16,980,000 which expire in 2008 through 2024. At June 30, 2004, the Company had available for federal income tax purposes approximately \$87,000 of alternative minimum tax credit carryforwards which carry forward indefinitely and approximately \$111,000 of tax credit carryforwards which expire in the years 2007 through 2009. The Company also has approximately \$11,476,000 of state net operating loss carryforwards, which expire in 2004 through 2019,

available to offset certain future state taxable income.

The income tax provision consists of the following:

| | 2004 | 2003 | 2002 |
|----------------------------|------|------|------|
| Current | | | |
| Federal | \$ 0 | \$ 0 | \$ 0 |
| State | 0 | 0 | 0 |
| Total income tax provision | \$ 0 | \$ 0 | \$ 0 |

A reconciliation of the provision for income taxes (benefit) at the federal statutory income tax rate to the effective income tax rate follows:

| | 2004 | 2003 | 2002 |
|--|---------|---------|---------|
| Federal statutory income tax rate | (34.0)% | (34.0)% | (34.0)% |
| Losses for which no benefit was provided | 57.6 | 33.0 | 51.9 |
| Non-deductible losses of subsidiaries | 0.0 | 0.0 | 0.0 |
| Other - net (principally stock options in 2004 and 2002) | (23.6) | 1.0 | (17.9) |
| Effective income tax rate | 0% | 0% | 0% |

6. LINE OF CREDIT FACILITY

At June 30, 2004, the Company had a \$2,500,000 demand line of credit facility with a commercial bank to meet its short-term borrowing needs. Borrowings against the line were payable on demand with interest payable monthly at the bank's reference rate, plus .25% (4.00% as of June 30, 2004). As of June 30, 2004, 2003, and 2002 there were no borrowings against the line. Borrowings under the line of credit facility are collateralized by substantially all assets of the Company. The credit facility has covenants which require minimum levels of tangible net worth and income levels. The Company was not in compliance with the covenants at June 30, 2004. Subsequent to year end, the demand line of credit facility was reduced to \$1,000,000 and the non-compliance was waived by the lending institution.

7. 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.

On July 1, 2004, the Company signed an agreement in the amount of \$200,000 to settle allegations that monitoring systems purchased from Criticare in fiscal 1999 did not perform to specifications. The Company paid \$50,000 in July upon execution of the agreement and agreed to pay the balance in three equal monthly installments of \$50,000 each, payable on the first day of each month beginning in August until the entire sum is paid.

Additionally, from time to time, various lawsuits arise out of the normal course of business. These proceedings are handled by outside counsel. Currently management is not aware of any claim or action pending against the Company that would have a material adverse effect on the Company.

8. STOCKHOLDERS' EQUITY

Stock Options - At the annual stockholders meeting held on November 14, 2003, the Company's shareholders approved the Criticare Systems, Inc. 2003 Stock Option Plan (the "2003 Plan"). This 2003 Plan replaced the 1992 Employee Stock Option Plan and the 1992 Non-Employee Stock Option Plan (collectively, the "1992 Plans") and 179,380 reserved shares of common stock available under the 1992 Plans were moved to the 2003 Plan. The shareholders also approved 250,620 shares being available for future grants in addition to the 179,380 shares currently available, for a total of 430,000 shares authorized for issuance under the 2003 Plan. The Company also has options outstanding under two plans which existed prior to the approval of the 1992 Plans, the 1987 Employee Stock Option Plan and the 1987 Non-Employee Stock Option Plan (collectively with the 1992 Plans, the "Old Plans"). As a result of the

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approval of the 2003 Plan, no new stock options can be granted under the Old Plans, although the Company can regrant existing stock options under the Old Plans to extend the term of such options. The Board of Directors has authorized in connection with these stock option plans the issuance of 2,710,620 reserved shares of common stock, of which 47,000 reserved shares remain available for future issuance at June 30, 2004. The Board of Directors increased the number of reserved shares for issuance under the stock option plans from 1,720,000 to 2,220,000 during 2001, from 2,220,000 to 2,460,000 during 2002, and from 2,460,000 to 2,710,620 during 2003. The activity during 2002, 2003 and 2004 for the above plans is summarized as follows:

| | Number of Shares | Stock Options Price Range | Weighted Avg. Exercise Price |
|------------------------------|---------------------|------------------------------|---------------------------------|
| Outstanding at June 30, 2001 | 1,635,620 | \$ 1.50-3.69 | \$ 2.19 |
| Granted | 35,000 | 3.60-4.40 | 4.21 |

| | | | |
|------------------------------|-----------|-----------|------|
| Cancelled | (57,700) | 1.63-2.97 | 2.43 |
| Exercised | (403,300) | 1.63-2.97 | 2.14 |
| Outstanding at June 30, 2002 | 1,209,620 | 1.50-4.40 | 2.26 |
| Granted | 273,950 | 2.88-3.11 | 2.91 |
| Cancelled | (52,700) | 2.97-3.62 | 3.18 |
| Exercised | (4,500) | 1.63 | 1.63 |
| Outstanding at June 30, 2003 | 1,426,370 | 1.50-4.40 | 2.35 |
| Granted | 414,000 | 3.05-4.37 | 3.19 |
| Cancelled | (39,750) | 1.63-4.30 | 3.21 |
| Exercised | (370,725) | 1.50-2.97 | 1.66 |
| Outstanding at June 30, 2004 | 1,429,895 | 1.88-4.40 | 2.75 |

The following table summarizes information about stock options outstanding as of June 30, 2004:

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | |
|--------------------------|-------------------------------------|---|---------------------------------|-------------------------------------|---------------------------------|
| | Shares Outstanding At June 30, 2004 | Weighted Average Contractual Life-Years Remaining | Weighted Average Exercise Price | Shares Exercisable at June 30, 2004 | Weighted Average Exercise Price |
| \$1.88-2.88 | 668,275 | 1.97 | \$ 2.33 | 441,210 | \$ 2.20 |
| 2.97-4.40 | 761,620 | 5.80 | 3.12 | 302,120 | 3.08 |
| 1.88-4.40 | 1,429,895 | 4.01 | 2.75 | 743,330 | 2.56 |

The weighted average exercise price of exercisable options at June 30, 2004, 2003, and 2002 was \$2.56, \$2.18, and \$2.13, respectively.

Outstanding options have fixed terms and are exercisable over a period determined by the Compensation Committee of the Company's Board of Directors but no longer than ten years after the date of grant.

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," and the additional disclosures required by SFAS No. 148, "Accounting for Stock Based Compensation - Transition and Disclosure," but applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for its plans. The fair value of stock options is the estimated present value at the grant date using the Black-Scholes option-pricing model. The weighted average fair market value of the options granted during fiscal 2004, 2003, and 2002, along with the assumptions used, follows below:

| Years Ended June | | |
|------------------|------|------|
| 30, | | |
| 2004 | 2003 | 2002 |

| | | | |
|--|--------|--------|--------|
| Weighted average fair market value of options granted during the fiscal year ended June 30 | \$0.95 | \$0.69 | \$1.57 |
| Assumptions used: | | | |
| Expected volatility | 80.0% | 80.0% | 70.0% |
| Risk-free interest rate | 4.39% | 2.87% | 3.59% |
| Expected option life (in years) | 9.40 | 4.40 | 3.30 |

Stock Warrants - In February 1998, the Company executed a warrant agreement with a consultant. The warrant agreement provided for the issuance of warrants to purchase up to 150,000 shares of common stock at a price of \$3.00 per share. The warrant was exercisable as to 30,000 shares upon execution of the agreement and the warrants to purchase the remaining 120,000 shares were to be exercisable if certain performance parameters were achieved by February 1999. No such parameters were achieved. These warrants expired in February 2003, but were amended. The 30,000 warrants were extended for an additional five years with an exercise price of \$2.88 per share which represents the closing price of the Company's stock on the date the warrants were amended.

In December 2000, the Company executed another warrant agreement with the consultant. The warrant agreement provides for the issuance of warrants to purchase up to 70,000 shares of common stock at a price of \$1.875 per share. The warrant vests over a four year period in four equal increments each year on the anniversary date of the warrant. The warrant terminates as to any shares that are unvested at the time the consultant ceases to provide consulting services to the Company. As of June 30, 2004, 52,500 of these warrants were exercisable. Such warrants expire in December 2005.

Preferred Stock - The Company's Board of Directors has the authority to determine the relative rights and preferences of any series it may establish with respect to the 500,000 shares of \$.04 par value authorized preferred shares. No preferred stock is issued or outstanding.

On March 27, 1997, the Board of Directors of the Company declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of common stock of the Company. The dividend was made on April 24, 1997 to the stockholders of record on that date to purchase Preferred Stock ("Preferred") upon the occurrence of certain events. The Rights will be exercisable the tenth business day after a person or group acquires 20% of the Company's common stock, or makes an offer to acquire 30% or more of the Company's common stock. When exercisable, each right entitles the holder to purchase for \$25, subject to adjustment, one-hundredth of a share of Preferred for each share of common stock owned. Each share of Preferred will be entitled to a minimum preferential quarterly dividend of \$25 per share, but not less than an aggregate dividend of 100 times the common stock dividend. Each share will have 100 votes, voting together with the common stock. In the event of any merger, each share of Preferred will be entitled to receive 100 times the amount received per share of common stock. The Rights expire on April 1, 2007.

Common Stock Held in Treasury - At June 30, 2004 and 2003 the Company held in Treasury 124,728 and 130,192 shares of common stock, respectively. On February 28, 2002, the Criticare Board of Directors approved the purchase in the open market of up to 500,000 shares of Criticare common stock. At June 30, 2004 and 2003 the Company held in Treasury 76,223 shares of common stock purchased in accordance with this stock buyback program.

Subscriptions Receivable - Subscriptions receivable represents common stock issued in May 2002 to two directors of the Company, Milton Datsopoulos and Karsten Houm, related to expiring stock options. The shares were issued and promissory notes payable in the amount of \$112,500 were executed by each of the directors for the exercise price of the stock options. In February 2003 these two directors retired from the Board. After their retirement, the promissory notes were refinanced through the issuance of two new notes dated March 1, 2003. These promissory notes were paid in full in February 2004.

9. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan which covers substantially all employees. Company contributions to the plan are discretionary and determined annually by the Company's Board of Directors. The Company's contributions were approximately \$96,000, \$92,000, and \$87,000 in 2004, 2003 and 2002, respectively.

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10. BUSINESS AND CREDIT CONCENTRATIONS

Financial instruments which potentially subject the Company to concentrations of credit risks consist of cash, certificates of deposit, and accounts receivable. These financial instruments are carried at approximate fair value, less appropriate allowance, due to their short maturities.

The Company maintains cash balances which at times may exceed federally insured limits. As of June 30, 2004 and 2003, the Company held \$3,425,816 and \$3,461,015, respectively, in excess of federally insured limits. The Company's management evaluates the creditworthiness of the financial institutions in which it places its cash. The Company has not experienced any losses in such accounts and does not believe it is exposed to any significant credit risk for cash accounts.

The Company is a manufacturer of medical monitors and telemetry products whose customers include hospitals and alternative health care sites throughout the world. Although the Company's products are sold primarily to health care providers, concentrations of credit risk with respect to trade accounts receivable are limited due to the Company's large number of customers, their geographic dispersion, and the Company's credit evaluation process. The Company currently coordinates substantially all international sales and distribution activities through its headquarters in Waukesha, Wisconsin. Other than inventory and accounts receivable for the Company's operation in India totaling approximately \$1.5 million, identifiable assets located outside of the United States are insignificant in relation to the Company's total assets. Net export sales by geographic area are as follows:

| | 2004 | | 2003 | | 2002 |
|--------------------------------------|---------------|----|------------|----|------------|
| Europe and Middle East | \$ 7,164,000 | \$ | 7,812,000 | \$ | 6,861,000 |
| Pacific Rim | 1,389,000 | | 1,614,000 | | 1,292,000 |
| Canada and Central and South America | 3,246,000 | | 2,218,000 | | 2,193,000 |
| Export net sales | \$ 11,799,000 | \$ | 11,644,000 | \$ | 10,346,000 |
| U.S. net sales | 16,792,000 | | 16,919,000 | | 15,874,000 |
| Total net sales | \$ 28,591,000 | \$ | 28,563,000 | \$ | 26,220,000 |

Note: Sales in Europe and the Middle East have been combined above due to joint sales responsibility in these areas. No country made up more than 10% of the Company's total sales.

11. OTHER BUSINESS CONCENTRATIONS

During 1999, the Company entered into an OEM agreement with a customer. Sales to this customer approximated \$3,580,000, \$3,723,000, and \$3,507,000 in fiscal 2004, 2003, and 2002, respectively, which represented approximately 13% of the Company's total sales in each of these fiscal years. The Company had a receivable balance from this customer of \$295,463, \$396,775, and \$370,346 on June 30, 2004, 2003, and 2002, respectively, which represented 4%, 6%, and 6% of the Company's total receivables as of these dates.

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In fiscal 2001, the Company entered into agreements with two offshore contract manufacturing firms to supply finished products. A summary of the purchases and outstanding payables to these two companies for the years ended June 30, 2004, 2003, and 2002 follows below:

| | 2004 | 2003 | 2002 |
|--------------------------|--------------|--------------|--------------|
| Supplier I - Purchases | \$ 6,756,279 | \$ 6,710,734 | \$ 4,258,014 |
| % of total purchases | 30.0% | 25.6% | 19.0% |
| Accounts payable balance | \$ 1,227,116 | \$ 1,034,427 | \$ 796,557 |
| % of total payables | 37.9% | 45.5% | 34.2% |
| Supplier II - Purchases | \$ 1,115,484 | \$ 2,958,231 | 2,104,640 |
| % of total purchases | 5.0% | 11.3% | 9.4% |
| Accounts payable balance | \$ 200,978 | \$ 114,975 | \$ 242,694 |
| % of total payables | 6.2% | 5.1% | 10.4% |

12. COMMITMENTS

The Company leases various equipment under both operating leases and a capital lease, which expire at various dates through fiscal 2009.

On January 19, 2004 the Company entered into a lease agreement for the hardware and software for a new business system. This lease has been accounted for as a capital lease in accordance with SFAS No. 13, "Accounting for Leases". The following is an analysis of this capital lease:

| | June 30, 2004 | June 30, 2003 |
|-------------------------------|---------------|---------------|
| Machinery and equipment | \$ 333,840 | \$ --- |
| Less accumulated depreciation | (23,846) | --- |
| Net | \$ 309,994 | \$ --- |

Depreciation expense was \$23,846 in fiscal 2004.

In August 2002 the Company sold its facility headquartered in Waukesha, Wisconsin and leased back approximately 62% of the building's square footage through August 2007. Rent expense was \$328,268 in 2004 and \$280,854 in 2003 for the five year building lease and all other lease commitments.

The following is a schedule by years of the future minimum lease payments under this capital lease and future minimum rental payments required under operating leases, together with the present value of the net minimum lease payments at June 30, 2004:

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| Fiscal year ending June 30 | Capital Lease | Operating Leases |
|---|------------------|---------------------|
| 2005 | \$ 82,560 | \$ 332,662 |
| 2006 | 82,560 | 329,776 |
| 2007 | 82,560 | 321,206 |
| 2008 | 82,560 | 73,258 |
| 2009 and thereafter | 62,640 | 22,678 |
| Total minimum lease payments | \$ 392,880 | \$ 1,079,580 |
| Less amount representing interest | (70,398) | |
| Present value of net minimum lease payments | \$ 322,482 | |
| Less current portion at June 30, 2004 | 57,711 | |
| Long-term portion at June 30, 2004 | \$ 264,770 | |

During fiscal 2001 the Company entered into supply partnership agreements with two offshore contract manufacturing firms that exclusively manufacture medical devices in a regulated environment. These two firms manufacture specific products designated by the Company in accordance with formal purchase orders. The initial term of the agreements is for a period of three years and is automatically extended for additional periods of two years each, unless either party gives written notice at least sixty days prior to the end of the initial term or the then current extension term. To ensure an adequate supply of products manufactured by these companies is maintained, the agreements require that these firms keep on hand in their finished goods inventories one full month of supply of all products under current purchase orders. At June 30, 2004 and 2003, a one month supply of product maintained at these two firms would total approximately \$555,000 and \$486,000, respectively. In the event the Company would cancel a purchase order under either of these agreements, the Company would be required to purchase at cost all raw materials, work-in-progress and finished goods inventories for that purchase order. The total work in process and raw material inventory for these agreements is approximately \$555,000. In addition, any property or equipment that these firms purchased specifically for the production of the Company's products would be purchased at mutually agreed upon prices. There have not been any purchase order cancellations under these agreements.

13. 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. The Company had set up a standby letter of credit for \$300,000 on behalf of an International distributor it is working with in connection with this project. 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 International distributor 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.

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The Company also maintained a second standby letter of credit (SBLC) for \$300,000 on behalf of the International distributor that served as a guarantee to borrowings by the International distributor used to set up and market this project. This SBLC was to expire on November 1, 2003, but was renewed through November 1, 2004 on October 16, 2003. Due mainly to more favorable credit terms obtained from another bank, on December 24, 2003 this \$300,000 SBLC was cancelled and replaced by a \$400,000 SBLC guaranteeing a \$450,000 line of credit that expires on December 31, 2004. This standby letter of credit would only be called if the cash flows from the project were not adequate to fund the costs to support the project and the International distributor would not be able to retire the debt. Due to adverse events relating to the International distributor subsequent to the end of fiscal 2004, Criticare believes that the project will not generate sufficient cash flow to fund the International distributor's line of credit, which will lead to the standby letter of credit being called. Thus, Criticare has recognized a charge to other expenses in the amount of \$400,000 to reserve for the impending call of this letter of credit.

In addition, Criticare also has an outstanding receivable due from the International distributor relating to equipment sold by Criticare to the International distributor. Criticare believes it is unlikely it will be able to collect the receivable due from the International distributor or recover the equipment shipped. Accordingly, Criticare has set up an allowance for the expected write off in the amount of \$421,000. A reserve in the amount of \$90,000 has also been established to satisfy a claim for duties and Value Added Tax associated with importation of products into a foreign country on behalf of the International distributor.

In the fiscal second quarter ended December 31, 2003, the Company also set up two new standby letters of credit to two suppliers of medical equipment for the project totaling \$100,000. These two SBLC s were set up to secure payment for the suppliers and would only be called if the cash flows from the project were not adequate to fund equipment purchases from these suppliers. Currently no purchases have been made from either supplier. As of September 2, 2004, one standby letter of credit in the amount of \$35,000 was voluntarily canceled by the supplier.

14. QUARTERLY RESULTS - Unaudited

The following table contains quarterly information, which includes all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for a fair presentation.

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| | Quarters Ended (Unaudited) | | | | | | | |
|-----------|---------------------------------------|----------------------|------------------|----------------------|------------------|----------------------|------------------|----------------------|
| | June 30, 2004 | March 31, 2004 | Dec. 31, 2003 | Sept. 30, 2003 | June 30, 2003 | March 31, 2003 | Dec. 31, 2002 | Sept. 30, 2002 |
| | (in thousands, except per share data) | | | | | | | |
| Net sales | \$ 6,668 | \$ 6,571 | \$ 8,980 | \$ 6,372 | \$ 6,705 | \$ 6,504 | \$ 9,050 | \$ 6,304 |

| | | | | | | | | |
|--|---------|--------|-------|--------|---------|-------|-------|--------|
| Gross profit | 2,702 | 2,809 | 3,685 | 2,574 | 1,616 | 2,481 | 3,938 | 2,397 |
| Net (loss) income | (1,708) | (413) | 412 | (392) | (1,287) | 460 | 180 | (292) |
| Net (loss) income per common share: | | | | | | | | |
| --Basic and diluted | (0.15) | (0.04) | 0.04 | (0.04) | (0.11) | 0.04 | 0.02 | (0.03) |

The Company typically receives a substantial volume of its quarterly sales orders at or near the end of each quarter. In anticipation of meeting this expected demand, the Company usually builds a significant inventory of finished products throughout each quarter. If the expected volume of sales orders is not received during the quarter, or is received too late to allow the Company to ship the products ordered during the quarter, the Company's quarterly results and stock of finished inventory can be significantly affected.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Criticare Systems, Inc.:
Waukesha, Wisconsin

We have audited the accompanying consolidated balance sheets of Criticare Systems, Inc. as of June 30, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Criticare Systems, Inc. at June 30, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO Seidman, LLP
Milwaukee, Wisconsin
August 18, 2004 except Note 6 dated September 23, 2004

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

Item 9A. 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 upon 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 9B. OTHER INFORMATION.

Not applicable.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information regarding the executive officers and directors of the Company is incorporated herein by reference to the discussions under "Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," "Executive Officers," "Audit Committee Matters - Audit Committee Financial Expert" and "Corporate Governance Matters - Code of Business Ethics" in the Company's Proxy Statement for the 2004 Annual Meeting of Stockholders (the "Criticare Proxy Statement") which will be filed on or before October 28, 2004.

The Audit Committee of the Company's Board of Directors is an "audit committee" for purposes of Section 3(a)(58) of the Securities Exchange Act of 1934. The members of the Audit Committee are Dr. Higgins D. Bailey, Dr. N.C. Joseph Lai and Stephen K. Tannenbaum (Chairman).

Item 11. EXECUTIVE COMPENSATION.

Incorporated herein by reference to the discussion under "Executive Compensation" and "Compensation of Directors" in the Criticare Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Information regarding security ownership of certain beneficial owners and management is incorporated herein by reference to the discussion under "Security Ownership" in the Criticare Proxy Statement.

The following table summarizes share information for the Company's equity compensation plans as of June 30, 2004, including the 2003 Stock Option Plan, the 1992 Employee Stock Option Plan, the 1992 Non-Employee Stock Option Plan, the 1987 Employee Stock Option Plan, the 1987 Non-Employee Stock Option Plan and the Company's Employee Stock Purchase Plan.

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Equity Compensation Plan Information

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column) |
|--|---|---|---|
| Equity compensation plans approved by security holders | 1,429,895 shares | \$2.75 per share | 491,408 shares |
| Equity compensation plans not approved by security holders | 100,000 shares | \$2.18 per share | 0 shares |
| Total | 1,529,895 shares | \$2.71 per share | 491,408 shares |

As noted in the table above, the Company has issued warrants to a consultant which have not been approved by the Company's shareholders. The Company executed a warrant agreement with the consultant in December 2000 for the purchase of 70,000 shares of Common Stock at an exercise price of \$1.875 per share. The warrant vests annually on the anniversary date of the agreement over a four-year period. The warrant expires in December 2005. Any unvested shares under the warrant agreement terminate if the consultant ceases to provide services to the Company. In addition to the foregoing, the Company also extended warrants for the purchase of 30,000 shares of Common Stock issued to

the consultant expiring in February 2003 for an additional five years with an exercise price of \$2.88 per share.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Incorporated herein by reference to the discussion under "Executive Compensation-Employment Agreements" in the Criticare Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Incorporated herein by reference to the discussion under "Audit Committee Matters-Fees of Independent Auditors" in the Criticare Proxy Statement.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) The following documents are filed as part of this report:

1. Financial Statements. The following consolidated financial statements of the Company are included in Item 8 of this report.

Consolidated Balance Sheets - as of June 30, 2004 and 2003.

Consolidated Statements of Operations - for the years ended June 30, 2004, 2003 and 2002.

Consolidated Statements of Stockholders' Equity - for the years ended June 30, 2004, 2003 and 2002.

Consolidated Statements of Cash Flows - for the years ended June 30, 2004, 2003 and 2002.

Notes to consolidated financial statements.

Report of Independent Registered Public Accounting Firm.

2. Financial Statement Schedules:

Report of Independent Registered Public Accounting Firm.

Financial Statement Schedule for the years ending June 30, 2004, 2003 and 2002:

| <u>Schedule Number</u> | <u>Description</u> | <u>Page</u> |
|------------------------|--|-------------|
| II | Valuation and Qualifying Accounts and Reserves | 53 |

All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions, are inapplicable or the required information is shown in the financial statements or notes thereto, and therefore have been omitted.

3. Exhibits:

3.1 Restated Certificate of Incorporation of the Company (incorporated by reference to the Registration Statement 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).

10.1* 2003 Stock Option Plan (and form of stock option grant agreement).

10.2* 1999 Employee Stock Purchase Plan (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

10.3* 1992 Employee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-60644).

10.4* 1992 Nonemployee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-60214).

10.5* 1987 Employee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-33497).

10.6* 1987 Nonemployee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-40038).

10.7* Form of Executive Officer and Director Indemnity Agreement (incorporated by reference to the Company's Registration Statement on Form S-1, Registration No. 33-13050).

10.8* Employment Agreement of Emil H. Soika (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

10.9* Employment Agreement of Drew M. Diaz (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

10.10 Supply Partnership Agreement, dated as of August 1, 2000, between the Company and BioCare Corporation (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 2001).

10.11 Supply Agreement, dated as of October 26, 2000, between the Company and TriVirix International Limited (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 2001).

10.12 Employment Agreement of Joseph P. Lester (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002).

21 Subsidiaries.

23.1 Consent of BDO Seidman, LLP.

24 Power of Attorney (incorporated by reference to the signature page hereof).

31. 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 Joel D. Knudson, 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.

* Management contract or compensatory plan or arrangement.

** 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.

The Company filed no reports on Form 8-K during the quarter ended June 30, 2004.

(c) Exhibits.

The response to this portion of Item 15 is submitted as a separate section of this report.

(d) Financial Statement Schedules.

The response to this portion of Item 15 is submitted as a separate section of this report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By /s/ Emil H. Soika
Emil H. Soika, President
and Chief Executive Officer

Date: September 28, 2004

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Emil H. Soika and Joel D. Knudson, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|------------------------------------|---|--------------------|
| /s/ Emil H. Soika Emil H. Soika | President, Chief Executive Officer and Director (Principal Executive Officer) | September 28, 2004 |

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| | | |
|------------------------------|---|--------------------|
| /s/ Joel D. Knudson | Vice President-Finance and Secretary | September 28, 2004 |
| Joel D. Knudson | (Principal Financial and Accounting Officer) | |
| /s/ Dr. Higgins Bailey | Chairman of the Board and Director | September 28, 2004 |
| Dr. Higgins Bailey | | |
| /s/ N.C. Joseph Lai | Director | September 28, 2004 |
| N.C. Joseph Lai, Ph.D. | | |
| /s/ Stephen K. Tannenbaum | Director | September 28, 2004 |
| Stephen K. Tannenbaum | | |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Criticare Systems, Inc.:
Waukesha, Wisconsin

The audits referred to in our report dated August 18, 2004 except Note 6 dated September 23, 2004 relating to the consolidated financial statements of Criticare Systems, Inc., which is contained in Item 8 of this Form 10-K included the audit of the financial statement schedules listed in Item 15. These financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statement schedules based upon our audits.

In our opinion such financial statement schedules present fairly, in all material respects, the information set forth therein.

/s/ BDO Seidman, LLP
Milwaukee, Wisconsin
August 18, 2004

SCHEDULE II

CRITICARE SYSTEMS, INC.

VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED JUNE 30, 2004, 2003 AND 2002

| <u>Column A</u> | <u>Column B</u> | <u>Column C</u> | <u>Column D</u> | <u>Column E</u> |
|--|---------------------------------------|--------------------------------------|-------------------|---------------------------------|
| <u>Description</u> | <u>Balance at Beginning of Period</u> | <u>Charged to Costs and Expenses</u> | <u>Deductions</u> | <u>Balance at End of Period</u> |
| YEAR ENDED JUNE 30, 2002: | | | | |
| Allowance for doubtful accounts | \$ 1,000,000 | \$ (183,046) | \$ 516,954 | \$ 300,000 |
| Reserve for sales returns and allowances | \$ 60,000 | \$ 12,945 | \$ -- | \$ 72,945 |
| Reserve for obsolete inventory | \$ 325,000 | \$ 676,284 | \$ 55,284 | \$ 946,000 |
| YEAR ENDED JUNE 30, 2003: | | | | |
| Allowance for doubtful accounts | \$ 300,000 | \$ 38,566 | \$ 38,566 | \$ 300,000 |
| Reserve for sales returns and allowances | \$ 72,945 | \$ 5,000 | \$ -- | \$ 77,945 |
| Reserve for obsolete inventory | \$ 946,000 | \$ 1,752,352 | \$ 1,298,352 | \$ 1,400,000 |
| YEAR ENDED JUNE 30, 2004: | | | | |
| Allowance for doubtful accounts | \$ 300,000 | \$ 393,758 | \$ 433,758 | \$ 260,000 |
| Reserve for sales returns and allowances | \$ 77,945 | \$ -- | \$ -- | \$ 77,945 |
| Reserve for obsolete inventory | \$ 1,400,000 | \$ 509,001 | \$ 1,299,001 | \$ 610,000 |