CRITICARE SYSTEMS INC /DE/ Form 10-K September 28, 2007

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

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

	ANT TO SECTIONS 13 OR CURITIES EXCHANGE AC	
(Mark One)		
[x] ANNUAL REPORT PURSUA OF 1934.	NT TO SECTION 13 OR 15(c	d) OF THE SECURITIES EXCHANGE ACT
For the fiscal year ended June 30, 2007		
[] TRANSITION REPORT PUR ACT OF 1934.	SUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHANGE
For the transition period from to	_	
	Commission file number <u>1-3</u>	1943
	icare Systems, Inc gistrant as Specified in Its Char	ter)
Delaware	39	-1501563
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employ	ver Identification No.)
20925 Crossroads Circle, Suite 10 (Address of Principal Ex		53186 (Zip Code)
Registrant's tel	ephone number, including area	code: <u>262-798-8282</u>
Securities	registered pursuant to Section	12(b) of the Act:
Title of Each Class	Name of Each Exchang Which Registered	ge on
Voting Common Stock, \$.04 par value (together with associated	American Stock Excha	nge

Preferred Stock Purchase Rights)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [] No [X]
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes [] No [X]
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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Exchange Act Rule 12b-2. (Check one)
Large accelerated filer [] Accelerated filer [] Non-accelerated filer []
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes [] No [X]
The aggregate market value of the voting common stock held by nonaffiliates of the registrant as of December 29, 2006 (the last business day of the registrant's most recently completed second fiscal quarter) was \$35,549,668. Shares of voting common stock held as of December 29, 2006 by any person who was an executive officer or director of the Registrant as of December 29, 2006 has 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, 2007, there were 12,318,219 shares of the registrant's \$.04 par value voting common stock outstanding.
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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Annual Meeting of the Stockholders of the Registrant to be held November 27, 2007 are incorporated by reference into Part III of this report.

As used in this report, the terms "we," "us," "our," "Criticare" and the "Company" mean Criticare Systems, Inc. and its subsidiaries, unless the context indicates another meaning, and the term "common stock" means our common stock, par value \$0.04 per share.

Special Note Regarding Forward-Looking Statements

A number of the matters and subject areas discussed in this report 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 this report. These statements may be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "hope," "plan," "potential," "should," "estimate," "predict," "continue," "future," "will," "would" or the negative of these terms or other words of similar meaning. Such forward-looking statements are inherently subject to known and unknown risks and uncertainties. Our actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, those described under the caption "Risk Factors" in Item 1A of this report. We undertake no obligation to make any revisions to the forward-looking statements contained in this filing or to update them to reflect events or circumstances occurring after the date of this filing.

PART I

Item 1. BUSINESS.

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. The Company's VitalView telemetry system allows one nurse to monitor up to sixteen 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. In fiscal 2006, the Company released a new, next generation portable vital signs monitor (VitalCareTM 506N3) and a new, next generation portable multi-parameter vital signs monitor (nGenuity 8100E).

Criticare is implementing several business initiatives as part of its strategy to develop and distribute products for highly technical, growth oriented niche markets. Management believes that in order to be successful, marketing, distribution and sales partnerships in these areas are required. That effort has resulted in the execution of a number of agreements with original equipment manufacturers ("OEMs"). To capitalize on these business initiatives, modules and stand-alone monitors were developed and marketed for specific OEM customers. The Company views OEM agreements as a complementary component to our strategy to develop products for highly technical niche markets, and the OEM business has been a significant driver of the Company's growth.

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. Production shipments to our newest OEM partner, Fukuda Denshi, Inc. of Japan, began in August 2007. A second initiative is the development of a highly specialized monitoring system for medical imaging applications in an MRI environment. In 2003, Criticare entered into an agreement with an OEM, Medrad, Inc. ("Medrad"), to jointly develop and exclusively sell a highly specialized medical monitoring product to Medrad. In July 2004, Criticare shipped the initial prototypes of this monitoring product to Medrad and production shipments began in January 2005. Sales to Medrad have grown quickly and Medrad has become the Company's largest customer in fiscal 2007, fiscal 2006 and fiscal 2005. Following the acquisition, in July 2004, of Alaris Medical Systems, Inc. ("Alaris"), a long-time OEM customer, by Cardinal Health, Inc., the third initiative was implemented to develop an Acute Care distribution network in the U.S. to sell to markets previously served through Alaris. Following such acquisition, Cardinal Health exited the vital signs monitor business and signed a transition agreement with the Company, which enabled our new Acute Care distribution network the opportunity to sell to the former Alaris customer base. In conjunction with the transition agreement, in September 2005, we introduced a new portable vital signs monitor for the Acute Care market. Sales for the Acute Care market during fiscal 2007 and fiscal 2006 have approached the largest revenue year Criticare experienced under the Alaris OEM agreement and greatly exceeded our expectations.

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.

<u>VitalCareTM 506N3 Portable Vital Signs Monitors</u>. The Portable Vital Signs Monitor provides maximum versatility and cost effectiveness in a small, compact, portable, full-featured vital signs monitor configured to meet specific clinical needs. The unit is available in multiple configurations, with a choice of Criticare or Nellcor oximetry, ComfortCuffTM noninvasive blood pressure and temperature (either FILAC FasTempTM or Alaris TurboTemp). This unit is ideal for spot checking or continuously monitoring patients' vital signs.

nGenuity 8100E Multi Parameter Vital Signs Monitors. The full-featured Multi Parameter Vital Signs Monitor combines ECG, ComfortCuffTM noninvasive blood pressure, DOXTM digital oximetry, heart rate, temperature, respiration rate, and nurse call interface for a complete vital signs monitor for physician offices, clinics, transport and hospital applications. Optional features include arrhythmia and ST analysis and an integrated printer.

PoetTM 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, ComfortCuffTM noninvasive blood pressure, DOXTM digital oximetry, heart rate, temperature, respiration rate, and nurse call interface. Optional features include CO₂, CO₂/O₂ and invasive blood pressure monitoring and an integrated printer. The 8100 is well suited for busy departments that require basic vital signs monitoring to conscious sedation.

PoetTM IQ 8500 and PoetTM IQ2 8500Q Anesthetic Gas Monitors. The PoetTM IQ 8500 gas monitor is used in conjunction with the PoetTM 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 PoetTM 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. The operating systems 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 proprietary to the Company. These products are 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.

<u>Model 503DX and 504DX Pulse Oximeters</u>. 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.

<u>VitalViewTM Central Monitoring Station</u>. The VitalView central station makes it possible for one nurse or technician to monitor up to sixteen 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. In addition, the VitalView can be used as a wireless device or hardwired and has ST and arrhythmia analysis capabilities.

<u>Pulse Oximetry Sensors</u>. 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.

<u>WaterChekTM/Chek-Mate Filter System</u>. 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.

Marketing and Sales

<u>Domestic Sales</u>. At August 31, 2007, the Company's domestic sales force consisted of three employees and 54 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. With the development of an Acute Care distribution network, the Company is working to achieve a significant presence in U.S. hospitals that generally purchase medical equipment through large group purchasing organizations (GPOs). These GPOs contract large medical equipment suppliers who can provide not only medical monitors, but also other medical equipment and service needs (such as CT scanners and MRI equipment). In addition, Cardinal Health and Criticare signed a transition agreement which enabled Criticare's new Acute Care distribution network the opportunity to sell to the former Alaris customer base. Alaris, formerly the Company's largest customer, was acquired by Cardinal Health in 2004, and Cardinal Health subsequently made the decision to exit from vital signs monitor sales activities, since those products no longer fit within its core business strategy.

Criticare is implementing several business initiatives as part of its strategy to develop products for highly technical, growth oriented niche markets. Management believes that in order to be successful, marketing and sales partnerships in these areas are required. That effort resulted in the execution of a number of OEM agreements.

To capitalize on these business initiatives, the Company began to focus on selling to OEMs with the hiring of a senior manager, in 1999, to lead this effort. Modules and stand-alone monitors were developed and marketed for specific OEM customers. The Company views OEM agreements as a critical component to our strategy to develop products for highly technical niche markets, and the OEM business has been a significant driver of the Company's growth with net sales of \$7.3 million or 23.3% of total net sales in fiscal 2007, \$6.8 million or 21.7% of total net sales in fiscal 2006 and \$6.1 million or 22.9% of total net sales in fiscal 2005. In particular, sales of the Company's newly developed anesthesia products and a highly specialized monitoring system for medical imaging applications are expected to continue to be mainly for new OEM partners. In July 2004, Criticare shipped the initial prototypes of this monitoring product to Medrad. Medrad, the Company's OEM partner for medical imaging applications, was the Company's largest customer in fiscal 2007, 2006, and 2005, accounting for net sales of approximately \$6.3 million in fiscal 2007, which represented 20.0% of the Company's total net sales in fiscal 2007.

<u>International Sales</u>. 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 2007, Criticare sold its products, principally to hospitals, in over 71 countries through over 93 independent dealers.

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 outcomes.

In fiscal 2007, 34.0% of Criticare's net sales, or \$10.7 million, was attributable to international sales, of which 53.4% was from sales in Europe and the Middle East, 11.6% was from sales to Pacific Rim countries and 35.0% was from sales to Canada and Central and South America. In fiscal 2006 and 2005, 40.1% and 43.5%, 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 \$0.4 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.

<u>Service</u>, <u>Support and Warranty</u>. Criticare believes that customer service is a key element of its marketing program. At August 31, 2007, the Company had a customer service and technical support staff of 19 people at its Waukesha, Wisconsin facility. Customer service support is available 24 hours a day, seven days a week, in which numerous customers' technical problems are 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 an agreement with two offshore contract manufacturing firms located in Taiwan and Ireland, respectively, that exclusively manufacture medical devices in a regulated environment. During fiscal 2005, the Company ended the supply agreement with the contract manufacturing firm in Ireland. The contract manufacturing firm in Taiwan also has manufacturing capabilities in China. A portion of Criticare's production has been transitioned to China to continue to receive favorable pricing. The Company works closely with this firm to maintain product quality and reliability. This firm performs the same rigorous quality control testing at its 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 manufactures and assembles all proprietary medical devices and "made in the USA" requirements at the Company's facility in Waukesha, Wisconsin. In addition, the Company continues 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 the offshore manufacturer to deliver products on a timely basis could have a material adverse effect on the Company. However, the manufacturer has the ability to produce the Company's products in Taiwan and China. Therefore, the Company is not totally reliant on a single plant or single source to supply product. This factor, combined with the Company's ability to continue to manufacture at its headquarters in Waukesha, Wisconsin, reduces the Company's risk of supply interruption.

The Company has achieved certification under the International Organization for Standardization's (ISO) standard 13485:2003. The offshore contract manufacturing firm has achieved certification under ISO's standards 13485 and 2000. 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, 2007, the Company had an in-house research, development and engineering staff of 18 people. The Company's research, development and engineering expenditures were \$2.4 million in fiscal 2007, \$2.4 million in fiscal 2006 and \$2.6 million in fiscal 2005.

Research and development efforts for fiscal 2007 focused on the development and release our next generation full featured vital signs monitor, our design of a high quality, reasonably featured and low cost portable vital signs monitor, and an upgrade to the portable multi-parameter vital signs monitor to provide a option with CO2. Research and development efforts for fiscal 2006 focused on the development and release our next generation portable multi-parameter vital signs monitor (nGenuity 8100E), our next generation portable vital signs monitor (VitalCareTM 506N3), and an upgrade to the MRI monitor to provide additional technological enhancements. Research and development efforts for fiscal 2005 focused on the development and release of the Veris MRI compatible vital signs monitor.

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 direct 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 (<u>i.e.</u>, 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 Company, Andros Incorporated, and Dräger Medical as the principal competitors. The market for vital signs monitors includes competitors such as General Electric Company, Dräger Medical, Datascope Corp., Philips Electronics, Welch Allyn Inc., Mindray Medical International Limited, CAS Medical Systems, Inc., Nihon Kohden Corporation and Spacelabs Medical, Inc., a subsidiary of OSI Systems, Inc. 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 U.S. Food and Drug Administration ("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 the FDA. If the FDA believes that its legal requirements have not been fulfilled, it has extensive enforcement powers, including the ability to ban or recall products from the market and to prohibit the operation of manufacturing facilities. The Company believes its products comply with applicable FDA regulations in all material respects. In addition, the Company received ISO 9002 certification on April 29, 1993, ISO 9001 certification on July 8, 1994 and ISO 13485:2003 certification on January 16, 2006.

Under the Federal Food, Drug and Cosmetic Act, 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 subjected. 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 Class III 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 Union. 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 20 issued U.S. patents and 1 U.S. patent pending. The Company's U.S. patents expire between 2007 and 2022. Criticare also has 14 issued foreign patents and 9 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 "CRITICARE", "POET", "POET IQ", "MPT", "REMOTEVIEW", "MICROVIEW", "VITALVIEW", "SCHOLAR", and "WATERCHEK".

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

Employees

At August 31, 2007 Criticare, had 95 employees in the U.S., including 18 in research, development and engineering, 19 in customer service and support, 27 in manufacturing and operations, 14 in administration, 9 in sales and marketing, and 8 in quality control. Criticare also utilizes four international country managers that work as independent contractors to support its international sales efforts. The Company also has an operation in India with 3 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, 2007 and 2006 was \$4,789,244 and \$5,260,197, respectively. The backlog is driven by the extended delivery schedule from Medrad, which totaled \$1,170,546 as of June 30, 2007 and \$4,100,984 as of June 30, 2006. 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 1A. RISK FACTORS

An investment in our common stock is subject to risks inherent in our business, including the risks described below. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In such cases, the trading price of our common stock could decline.

Risks Related to Our Business

Our net sales and profitability depend on our ability to conceive, design and market new products.

The introduction of new products is critical to our growth strategy. Our future success will depend in large part upon our ability to conceive, design, and market new products and upon market acceptance of our existing and future products. Any significant delays in the introduction of, or the failure to introduce, new products or additions to our existing product lines or the failure of our existing or future products to maintain or receive market acceptance could have a material adverse effect on our net sales and profitability.

Our future success will depend on our ability to compete effectively in our industry.

The medical equipment industry is highly competitive. Many of our competitors have greater financial and other resources, more established brand identities and reputations, greater development capabilities, more experience in testing products and obtaining regulatory approvals, and larger and more experienced sales forces than us. In these respects, such companies have a competitive advantage over us. In addition, internationally there are many in-country manufacturers that supply duty and tariff-free low cost monitors that make it difficult for us to be price competitive in these countries. The medical equipment market is also experiencing increasing customer concentration, due to the emergence of large purchasing groups, which can increase the barriers for a small company such as Criticare. If we cannot compete successfully in the future, our net sales and profitability will likely decline.

Our business may be adversely affected by the highly regulated environment in which we operate.

Our products are subject to regulation by the United States Food and Drug Administration and comparable foreign governmental authorities. These regulations can be burdensome and may:

substantially delay or prevent the introduction of new products; materially increase the costs of any new product introductions; interfere with or require cessation of product manufacturing and marketing; and result in product recalls.

Additionally, adoption of new regulations or modifications to applicable regulations could harm our business. Some of the legislative and regulatory changes may benefit us and our competitors; other changes, however, could have a material adverse effect on our business, financial condition and results of operation and/or provide an advantage to certain of our competitors.

Since we sell product in foreign markets, we are subject to foreign currency and other international business risks that could adversely affect our operating results.

International sales account for a significant portion of our total net sales each fiscal year. We expect that international sales will continue to constitute a significant portion of our business. Although our net sales are primarily denominated in United States dollars and are not subject to significant currency risks, an increase in the value of the United States dollar relative to foreign currencies in our international markets could make our products less price competitive in such markets. Our international sales are subject to the risks inherent in doing business abroad, including:

complications in complying with the laws and policies of the United States and foreign governments affecting foreign trade, including duties, quotas, taxes and export controls;

unexpected changes in international regulatory requirements and tariffs; difficulties in staffing and managing foreign operations; political or economic changes, especially in developing nations; and price controls and other restrictive actions by foreign governments.

Any of these risks might disrupt sales of our products, increase our expenses or decrease our revenues.

Our reliance on offshore contract manufacturing makes our business susceptible to numerous risks that could affect our profitability.

In response to pricing pressure, in fiscal 2001 we entered into agreements for offshore contract manufacturing. We completed the transition of the offshore production of substantially all of our established product lines at the end of calendar 2001. Currently, our offshore manufacturing is handled by a contract manufacturing firm in Taiwan that also has manufacturing capabilities in China. Any inability of the offshore manufacturer to deliver products on a timely basis could have a material adverse effect on us.

Our reliance on offshore contract manufacturing will subject us to numerous risks, including the following:

economic and political instability in the countries where the contract manufacturing firms are located; restrictive actions by foreign governments; the laws and policies of the United States affecting the importation of goods (including duties, quotas and taxes); production delays and cost overruns; quality control; and foreign trade and tax laws.

We depend on a major customer for a significant portion of our sales.

In fiscal 2007, our largest customer accounted for net sales of approximately \$6.3 million, which represented 20.0% of our total net sales. We also had a receivable balance with this customer of approximately \$1.6 million as of June 30, 2007, which represented 27.7% of our total receivables as of that date. An adverse change in our relationship with or the financial viability of our largest customer could have a material adverse effect on our net sales and profitability.

As a manufacturer and marketer of medical equipment, we could experience product liability claims.

The nature of our products may expose us to significant product liability risks. Although, we maintain product liability insurance, we can make no assurance that we will be able to maintain this insurance on acceptable terms or that the insurance will provide adequate coverage against product liability claims. A successful product liability claim against us in excess of our insurance coverage could be extremely damaging to us. Even if a product liability claim is without merit, the claim could harm our reputation and divert management's attention and resources from our business.

Our success depends on our ability to protect our intellectual property.

We rely on our patented and other proprietary technology including:

our sensor technology; infrared specific anesthetic gas monitoring technology; UltraSync signal processing software; and disposable respiratory secretion filter system.

The actions taken by us to protect our proprietary rights may not be adequate to prevent imitation of our products, processes or technology. We can not assure you that:

our proprietary information will not become known to competitors; others will not independently develop substantially equivalent or better products that do not infringe on our intellectual property rights; or

others will not challenge or assert rights in, and ownership of, our patents and other proprietary rights.

Health care cost containment programs could adversely affect our domestic sales.

The cost of a significant portion of medical care in the United States is funded by government or other insurance programs. Additional limits imposed by such programs on health care cost reimbursements may further impair the ability of hospitals and other health care providers to purchase equipment such as our products and could reduce our domestic sales.

Our controls and procedures may be ineffective.

Our management regularly reviews and updates our internal control over financial reporting, disclosure controls and procedures, and corporate governance policies and procedures. We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which will require annual management assessments of the effectiveness of our internal control over financial reporting beginning with our annual report for fiscal 2008 and annual attestation reports by our independent auditors addressing the effectiveness of our internal control over financial reporting beginning with our annual report for fiscal 2009. We expect our efforts to achieve initial compliance with these provisions will require a significant commitment of management resources and will result in significant additional expenses over the next two fiscal years. We may not be able to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act by the required deadlines. Further, any system of controls, no matter how well designed and operated, is based partly on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of our controls and procedures or failure to comply with regulations related to controls and procedures could have a material adverse effect on our business, results of operations, and financial condition.

Risks Related to an Investment in our Common Stock

The trading price of our common stock has been volatile and investors in our common stock may experience substantial losses.

The market price of our common stock has experienced significant volatility from time to time. There may be volatility in the market price of our common stock due to factors that may or may not relate to our performance. The trading price of our common stock could decline or fluctuate in response to a variety of such factors, including:

the timing of announcements by us or our competitors concerning significant acquisitions, financial performance or the introduction of new innovative products or services;

fluctuation in our quarterly operating results; fluctuations in demand for our products; fluctuations in interest rates; substantial sales of our common stock; or general stock market or other economic conditions.

You may be unable to sell your stock at or above your purchase price.

Various restrictions in our certificate of incorporation and by-laws, our rights plan and Delaware law could prevent or delay a change in control of us which is not supported by our Board of Directors.

Provisions of our certificate of incorporation and by-laws may make it more difficult for a third party to gain control or acquire us without the consent of our board of directors, even if such a transaction may be perceived as beneficial to our stockholders. These provisions include a Board of Directors divided into three classes of directors serving staggered terms of three years each.

Each currently outstanding share of our common stock includes, and each newly issued share of our common stock will include, one preferred share purchase right. The rights are attached to and trade with the shares of common stock and generally are not exercisable. The rights will become exercisable the tenth business day after a person or group acquires 20% or more of our common stock or makes an offer to acquire 30% or more of our common stock. When exercisable, each right entitles the holder to purchase for \$25, subject to adjustment, $1/100^{th}$ of a share of preferred stock for each share of common stock owned. The rights have anti-takeover effects and generally will cause substantial dilution to a person or group that attempts to acquire control of us without conditioning the offer on either redemption of the rights or amendment of the rights to prevent this dilution. The rights could have the effect of delaying or preventing a change of control. The rights are scheduled to expire on March 27, 2017.

We are also subject to Section 203 of the Delaware General Corporation Law which prohibits a merger, consolidation, asset sale or other similar business combination between Criticare and any stockholder of 15% or more of our common stock for a period of three years after the stockholder acquires 15% or more of our common stock, unless (1) the transaction is approved by our board of directors before the stockholder acquires 15% or more of our common stock, (2) upon completing the transaction the stockholder owns at least 85% of our common stock outstanding at the commencement of the transaction, or (3) the transaction is approved by our board of directors and the holders of 66 2/3% of our common stock excluding shares of our common stock owned by the stockholder.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES.

In August 2002, the Company leased approximately 37,000 square feet of a building in Waukesha, Wisconsin to serve as the Company's headquarters, warehouse, manufacturing, research and development and service facility. The lease originally was to expire on August 30, 2007, but the Company exercised its option to extend the lease for an additional three years so that the lease now expires on August 31, 2010. The Company currently leases approximately 32,000 square feet, with rent currently totaling \$23,545 per month. The Company has also leased approximately 8,800 square feet of a building near the Company's headquarters to serve as an additional warehouse facility. This lease expires on August 31, 2010, with rent totaling \$4,925 per month for the term of the lease.

Item 3. LEGAL PROCEEDINGS.

In the normal course of business Criticare may be involved in various legal proceedings from time to time. Criticare does not believe it is currently involved in any claim or action the ultimate disposition of which would have a material adverse effect on 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, 2007.

PART II

<u>ItemMARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 5. ISSUER PURCHASES OF EQUITY SECURITIES.</u>

The Company's common stock trades on the American Stock Exchange under the symbol "CMD". As of June 30, 2007, there were approximately 183 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 following table shows the high and low closing prices of the Company's common stock as reported by the American Stock Exchange for the periods indicated.

	Years Ended June 30,	
2007		2006

Quarter Ended:	Hi	gh	Low	High	Low
September 30	\$	4.25	\$ 2.79	\$ 5.34	\$ 4.14
December 31	\$	4.25	\$ 2.94	\$ 5.15	\$ 4.62
March 31	\$	3.83	\$ 3.11	\$ 5.30	\$ 4.55
June 30	\$	3.81	\$ 3.20	\$ 5.09	\$ 3.58

ItemSELECTED FINANCIAL DATA.

<u>6</u>.

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

	Years Ended June 30,									
	200)7		2006		2005		2004		2003
Net sales	\$ 31,43	31,810	\$	31,350,919	\$ 2	26,781,627	\$	28,591,481	\$	28,562,943
Net income										
(loss)	34	18,027		212,118		(422,245)		(2,100,573)		(938,596)
Net income (loss) per common										
share										
basic and										
diluted	\$	0.03	\$	0.02	\$	(0.04)	\$	(0.19)	\$	(0.08)
Average shares outstanding										
basic	12,29	99,411		12,069,060		11,514,786		11,240,685		11,071,735
diluted	12,33	32,296		12,256,431		11,514,786		11,240,685		11,071,735
Stockholders'										
equity	\$ 16,31	0,754	\$	15,853,086	\$	14,209,140	\$	13,789,300	\$	15,034,208
Long-term										
obligations	4	59,678		134,485		210,592		286,417		38,662
Working										
capital	14,04	19,063		13,322,276		12,339,332		11,756,441		12,895,476
Total assets	21,64	18,523		22,979,078		19,060,473		19,542,341		18,762,327

<u>Item 7.</u> <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.</u>

The following discussion is intended to provide an analysis of our financial condition and results of operations and should be read in conjunction with our financial statements and the notes to our financial statements included in Item 8 of this report. The discussion also includes forward-looking statements. As indicated on the cover page of this report under "Special Note Regarding Forward-Looking Statements," undue reliance should not be placed on forward-looking statements.

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 physicians offices, and nursing homes. Criticare is implementing several business initiatives as part of its strategy to develop and distribute products for highly technical, growth oriented niche markets. Management believes that in order to be successful, marketing and sales partnerships in these areas are required. That effort resulted in the execution of a number of OEM agreements.

Criticare is implementing several new business initiatives as part of its strategy to develop and distribute products for highly technical growth oriented niche markets. To capitalize on these business initiatives, modules and stand-alone monitors were developed and marketed for specific OEM customers. The Company views OEM agreements as a critical component to our strategy to develop products for highly technical niche markets, and the OEM business has been a significant driver of the Company's growth with net sales of \$7,335,059 or 23.3% of total net sales in fiscal 2007, \$6,814,623 or 21.7% of total net sales in fiscal 2006 and \$6,132,122 or 22.9% of total net sales in fiscal 2005.

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. Production shipments to our newest OEM partner, Fukuda Denshi, Inc. of Japan, began in August 2007. A second initiative is the development of a highly specialized monitoring system for medical imaging applications in an MRI environment. In 2003, Criticare entered into an agreement with Medrad to jointly develop and exclusively sell a highly specialized medical monitoring product to Medrad. In July 2004, Criticare shipped the initial prototypes of this monitoring product to Medrad and production shipments began in January 2005. Medrad was the Company's largest customer in fiscal 2007, 2006 and 2005, accounting for 20.0%, 16.5% and 11.6%, respectively, of the Company's net sales in those fiscal years. Following the acquisition, in July 2004, of Alaris Medical Systems, Inc., a long-time OEM customer, by Cardinal Health, Inc., the third initiative was implemented to develop an Acute Care distribution network in the U.S. to sell to markets and group purchasing organizations (GPO's) previously served through Alaris. Following such acquisition, Cardinal Health exited the vital signs monitor business and signed a transition agreement with the Company, which enabled our new Acute Care distribution network the opportunity to sell to the former Alaris customer base. In conjunction with the transition agreement, in September 2005, we introduced a new portable vital signs monitor for the Acute Care market. Sales for the Acute Care market totaled approximately \$3.16 million during fiscal 2007 and \$3.49 million during the introduction year of fiscal 2006. This key initiative will remain ongoing as the Company works to obtain and maintain tier I and tier II GPO contracts which will allow the net sales for the Acute Care network to exceed the largest revenue year Criticare experienced under the Alaris OEM agreement.

The Company posted total net sales of \$7,640,927 for the fourth quarter of fiscal 2007, which were 7.7% higher than the \$7,095,962 in net sales for the same period of fiscal 2006, principally due to the strong OEM and international sales in fiscal 2007. The Company reported a net loss of \$(365,709) for the fourth quarter of fiscal 2007 as compared to a net loss of \$(524,220) for the fourth quarter for fiscal 2006. For the full year, the Company had total net sales of \$31,431,810 in fiscal 2007 compared to net sales of \$31,350,919 in fiscal 2006. Additionally, for the second consecutive year the Company posted net income, with net income of \$348,027 in fiscal 2007 compared to net income of \$212,118 in fiscal 2006.

Results of Operations

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

		Percentage of Net Sales Years Ended June 30,						
	2007	2006	2005					
Net sales	100.0%	100.0%	100.0%					
Cost of goods sold	62.5	61.6	60.9					
Gross profit	37.5	38.4	39.1					
Operating expenses:								
Sales and marketing	19.1	22.2	21.2					
Research, development and								
engineering	7.6	7.5	9.8					
Administrative	10.9	10.1	10.8					
Total	37.6	39.8	41.8					
Loss from operations	(0.1)	(1.4)	(2.7)					
Interest expense	0.0	(0.1)	(0.1)					
Interest income	0.4	0.3	0.2					
Foreign currency exchange gain								
(loss)	0.5	(0.3)	0.5					
Other income	0.3	2.2	0.5					
Income (loss) before income								
taxes	1.1	0.7	(1.6)					
Income tax provision								
Net income (loss)	1.1%	0.7%	(1.6)%					

Fiscal Year Ended June 30, 2007 Compared to June 30, 2006

Net sales increased \$80,891 to \$31,431,810 for fiscal 2007 compared to \$31,350,919 for fiscal 2006. The increase resulted from a 5.3% increase in the average sales price per unit, which was partially offset by a 3.9% decrease in accessory sales and a 1.0% decrease in the number of units shipped in the current year. The increased sales were driven by a \$1,093,031 increase in domestic alternate care sales and a \$520,436 increase in OEM sales, which were partially offset by a \$1,027,626 decrease in international sales and a \$335,453 decrease in acute care sales during fiscal 2007. OEM sales in fiscal 2007 were \$7,335,000 and represented 23.3% of total net sales, compared to \$6,815,000 (21.7% of total net sales) in fiscal 2006. The OEM sales of \$6,290,137 to Medrad in fiscal 2007, for medical imaging applications, increased \$1,110,258 from fiscal 2006. The increased domestic alternate care sales was due to a number of factors, including Criticare's release of our next generation portable multi-parameter vital signs monitor and the initial order to replace all vital signs monitors in over 50 domestic plasma collection centers. International sales were lower than expected, due in large part to a \$1,874,000 partial shipment of an order from the ministry of health of the Republic of Iraq which shipped in the fourth quarter of fiscal 2007, but which did not meet all the strict criteria for revenue recognition in accordance with SAB No. 104. Due to the size and risks associated with a contract of this nature, the Company obtained a confirmed letter of credit to secure payment. As a result, while the order met the revenue recognition criteria of ensuring collectibility, the terms of the letter of credit

did not allow the transfer of title to occur until after June 30, 2007. The majority of this sale will be included in the first quarter results for fiscal 2008.

The gross profit percentage of 37.5% realized in fiscal 2007 decreased from the 38.4% generated in the prior year. Margins decreased in the current year as the positive effect of a slight change in product mix was offset the continued upward shift in fixed overhead costs to meet the increased quality and production demands of our OEM customers and the increased overhead costs associated with manufacturing start-up costs related to our new portable multi-parameter vital signs monitor.

Charges to cost of goods sold for potentially obsolete inventory totaled \$ 167,144 in fiscal 2007 compared to \$56,622 in fiscal 2006. Inventory considered obsolete will be disposed of and removed from Criticare's warehouse during fiscal 2008.

Operating expenses for the year ended June 30, 2007 decreased \$672,357 from fiscal 2006 due mainly to a decrease of \$941,355 in sales and marketing expenses, which was partially offset by an increase of \$257,165 in administrative expenses. The increase of \$257,165 in administrative expenses was due to the \$451,564 of expenses incurred during the year in connection with the two consent solicitation actions initiated by BlueLine Partners and the subsequent settlement of those actions in the third quarter. The decrease of \$941,355 in sales and marketing expenses was due mainly to a \$528,709 decrease in bad debt expenses from the reserve established in fiscal 2006 of a portion of the receivable due from one of our distributors with no corresponding reserve in fiscal 2007, a \$135,676 decrease in India operation expenses, a \$112,695 decrease in commissions earned and a \$83,178 decrease in advertising and trade show expenses for the year ended June 30, 2007. In fiscal 2006, the Company reserved a portion of the receivable due from the distributor referred to in the previous sentence, in the amount of \$529,700. Due to a reduction in the receivable from the distributor, the reserve has been reduced to \$227,638 as of June 30, 2007.

Total other income for the fiscal year ended June 30, 2007 decreased \$273,525 from fiscal 2006. This decrease was mainly due to the \$300,000 received pursuant to a patent license agreement in fiscal 2006 with no corresponding income in fiscal 2007, and a decrease of \$295,400 in royalty income partially offset by an increase of \$41,395 in interest income and a foreign currency exchange gain of \$171,361 in fiscal 2007 related to the Company's operation in India, which had a foreign currency exchange loss of \$(108,225) in fiscal 2006.

Loss from operations of \$(38,055) for the year ended June 30, 2007 decreased \$409,434 as compared to a loss from operations of \$(447,489) for the same period in fiscal 2006, which was the result of a decrease of \$672,357 in operating expenses and a decrease in gross profit of \$262,923. The decreased loss from operations was partially offset by the decrease in other income of \$273,525, resulting in net income of \$348,027 for the year ended June 30, 2007 as compared to net income of \$212,118 for fiscal 2006.

Fiscal Year Ended June 30, 2006 Compared to June 30, 2005

Net sales increased \$4,569,292 to \$31,350,919 for fiscal 2006 compared to \$26,781,627 for fiscal 2005. The increase resulted from a 3.5% increase in the number of units shipped, a 11.7% increase in the average sales price per unit and a 6.5% increase in accessory sales in the current year. The increased sales were in part the result of \$3,492,754 in acute care sales, which are a successful result of Criticare's business initiative to develop an acute care distribution network in the U.S. to sell to markets previously served through Alaris. Additionally, the increased sales were driven by a \$827,941 increase in international sales and a \$682,501 increase in OEM sales, which were partially offset by a \$1,025,778 decrease in domestic alternate care sales during fiscal 2006. The international sales increased despite a \$357,972 reduction of sales in India during fiscal 2006. The OEM sales of \$5,179,879 to Medrad, for medical imaging applications, was partially offset by reduced sales of \$2,034,468 to Alaris, formerly our largest OEM customer, during fiscal 2006. The decrease in domestic alternate care sales was due to a number of factors, including Criticare's movement to exit the defibrillator market due to the continued trend of direct sales by defibrillator manufacturers rather than through an establish distribution network, the postponed sales of patient monitors awaiting the release of our next generation portable multi-parameter vital signs monitor and the overall maturation of the oral surgery market. OEM sales in fiscal 2006 were \$6,815,000 and represented 21.7% of total net sales, compared to \$6,132,000 (22.9% of total net sales) in fiscal 2005.

The gross profit percentage of 38.4% realized in fiscal 2006 decreased from the 39.1% generated in the prior year. The margins decreased in the current period as the positive effect of a slight change in product mix was offset by the adverse effect of increased overhead costs associated with the manufacturing start-up costs related to our new portable vital signs monitor and the portable multi-parameter vital signs monitor, the replacement of a key supplier and with an upward shift in the fixed overhead costs to meet the increased quality and production demands of our OEM customers.

Charges to cost of goods sold for potentially obsolete inventory totaled \$56,622 in fiscal 2006 compared to \$281,003 for fiscal 2005. Inventory considered obsolete will be disposed of and removed from Criticare's warehouse during fiscal 2007.

Operating expenses for the year ended June 30, 2006 increased \$1,293,377 from fiscal 2005 as an increase of \$1,279,806 in sales and marketing and \$271,193 in administrative expenses was partially offset by a \$257,622 reduction in research, development and engineering expenses. The increase of \$1,279,806 in sales and marketing expenses was due mainly to a \$354,918 increase in the commissions earned due to increased sales and a \$148,113 increase in India operation expenses, combined with a \$98,277 increase in advertising, trade shows and sales promotion and a \$19,154 increase in license fees spending for the year ended June 30, 2006. In addition, due to the political climate currently in Mexico and the age of the receivable, we have reserved a portion of a receivable from one of our distributors in the amount of \$529,700, which has significantly increased our sales and marketing expenses. Administrative expenses increased by \$271,193 mainly due to an increase of \$316,096 in compensation expenses of which \$172,988 was recognized in conjunction with stock options under SFAS 123(R), an increase of \$38,406 in license fees and an increase of \$37,500 in board of director fees, which was partially offset by a \$99,211 reduction in legal fees and a \$26,506 reduction in recruiting fees. The increase in operating expenses was partially offset by a decrease of \$257,622 in research, development and engineering expenses. In the first quarter of fiscal 2005, Criticare received funding of \$125,000 from our largest OEM customer to jointly develop a highly specialized monitoring system for medical imaging applications, which reduced the research, development and engineering expenses for the year ended June 30, 2005 as compared to the year ended June 30, 2006.

Total other income for the fiscal year ended June 30, 2006 increased \$355,657 from fiscal 2005. This increase was mainly due to the \$300,000 received pursuant to a patent license agreement, an increase of \$136,297 in royalty income and an increase of \$36,120 in interest income, partially offset by a foreign currency exchange loss of \$(108,225) related to the Company's operation in India, which had a foreign currency exchange gain of \$131,885 in fiscal 2005.

The \$1,572,083 and \$355,657 increase in gross profit and total other income, respectively, partially offset by the increased operating expenses of \$1,293,377, resulted in net income of \$212,118 for the year ended June 30, 2006 as compared to a net loss of \$(422,245) for fiscal 2005.

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. Revenue is recognized in accordance with SAB No. 104, when all four elements for revenue recognition have been met. This revenue recognition policy is utilized for shipment of product to customers including both distributors and end-users.

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 2007, the reserve for obsolete inventory was increased \$15,000 to \$375,000 at June 30, 2007 due to normal variations in the inventory mix. During fiscal 2006, the reserve for obsolete inventory was decreased \$78,300 to \$360,000 at June 30, 2006 due mainly to the disposal of obsolete inventory that had been reserved for in prior years.

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, 2007, the Company had a cash balance of \$4,635,823 as compared with its fiscal 2006 year-end cash balance of \$3,793,781. The Company has continued to maintain a bank debt free balance sheet.

With the Company's return to profitability, Criticare has been able to increase its cash position by an aggregate of \$896,998 over the last three fiscal years. Non-cash expenses consisting primarily of depreciation expense, share based compensation expense as a result of SFAS 123(R), provision for obsolete inventory and provision for doubtful accounts decreased the Company's profitability by an aggregate of \$3,379,846 over 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 \$1,192,915 of capital spending primarily with \$2,147,192 of cash provided by the exercise of stock options over that period.

In fiscal 2007, \$1,255,824 of cash was generated from operations. This increase in cash was primarily driven by a combination of the reduction of the inventory, which was increased in fiscal 2006 due to the release of the next generation portable multi-parameter vital signs monitor, and the profitability of the Company. The cash generated from operations was partially offset by capital spending of \$407,473 and \$11,493 of cash used in financing activities. In fiscal 2007, \$62,655 of cash was generated from the issuance of 11,500 shares of common stock upon the exercise of stock options. In fiscal 2006, \$1,213,677 of cash was generated from the issuance of 473,045 shares of common stock upon the exercise of stock options, most of which were scheduled to expire in less than one year. This cash partially offset the \$408,544 of cash used in operations and the \$669,275 of capital spending in fiscal 2006. Cash used in operations in fiscal 2006 was primarily driven by the inventory investment in the new, next generation portable multi-parameter vital signs monitor. In fiscal 2005, \$688,724 of cash was generated from the issuance of 280,337 shares of common stock upon the exercise of stock options and an additional \$131,250 of cash was generated from the issuance of 70,000 shares of common stock upon the exercise of stock warrants, most of which were scheduled to expire in less than one year. This cash partially offset the \$726,064 of cash used in operations and the \$116,167 of capital spending in fiscal 2005.

The Company believes all near term 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, 2008. The Company also has a \$2,000,000 line of credit currently in place that could be utilized, if necessary. At June 30, 2007, there were no borrowings outstanding under this line of credit. The credit facility has covenants which require minimum income or liquidity levels. The Company was in compliance with the covenants at June 30, 2007. This line expires in June 2008.

The following table summarizes the Company's contractual cash obligations at June 30, 2007 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:

						2012 and
	Total	2008	2009	2010	2011	Thereafter
Operating leases	\$ 1,187,990	\$ 378,597	\$ 383,459	\$ 365,270	\$ 60,664	
Capital leases	145,200	82,560	52,140	10,500		
Contract Mfg obligations	350,000	350,000				
Other long-term obligations	5,476	5,476				
Total contractual						
obligations	\$ 1,688,666	\$ 816,633	\$ 435,599	\$ 375,770	\$ 60,664	

<u>ItemQUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.</u> 7A.

The Company has a demand line of credit facility with a commercial bank with interest payable monthly at 25 basis points below the bank's reference rate. The Company had no borrowings outstanding under this bank facility at June 30, 2007, 2006 and 2005. 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 operations in India which are 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, 2007. The Company does not use any hedges or other derivative financial instruments to manage or reduce exchange rate risk.

<u>ItemFINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.</u> <u>8</u>.

FINANCIAL STATEMENTS

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS JUNE 30, 2007 AND 2006

ASSETS (Note 6)	2007	2006
CURRENT ASSETS:		
Cash and cash equivalents (Notes 1 and 10)	\$ 4,635,823	\$ 3,793,781
Accounts receivable, less allowance for doubtful accounts		
of \$497,638 and \$829,700, respectively (Note 1)	5,991,999	6,446,637
Other receivables (Note 1)	251,950	331,722
Short-term note receivable (Note 1)	50,000	50,000
Inventories (Notes 1 and 2)	8,177,523	9,464,037
Prepaid expenses	219,859	227,606
Total current assets	19,327,154	20,313,783
PROPERTY, PLANT AND EQUIPMENT (Note 1):		
Machinery and equipment	3,415,501	3,157,328
Furniture and fixtures	946,668	952,193
Leasehold improvements	290,084	243,604
Demonstration and loaner monitors	2,025,924	1,997,844
Production tooling	2,389,507	2,294,360
Property, plant and equipment – cost	9,067,684	8,645,329
Less accumulated depreciation	6,877,295	6,193,015
Property, plant and equipment – net	2,190,389	2,452,314
OTHER ASSETS:		
License rights and patents – net (Notes 1 and 3)	55,980	62,981
Long-term note receivable (Note 1)	75,000	150,000
Total other assets	130,980	212,981
TOTAL ASSETS	\$ 21,648,523	\$ 22,979,078

See notes to consolidated financial statements.

LIABILITIES AND STOCKHOLDERS' EQUITY	2007	2006		
CURRENT LIABILITIES:				
Accounts payable	\$ 3,826,834	\$	5,408,746	
Accrued liabilities:				
Compensation and commissions	836,720		914,889	
Product warranties (Notes 1 and 4)	349,000		425,000	
Other	191,389		174,667	
Obligations under capital lease (Note 12)	74,148		68,205	
Total current liabilities	5,278,091		6,991,507	
LONG-TERM LIABILITIES:				
Obligations under capital lease, less current portion (Note 12)	59,678		133,826	
Other long-term obligations			659	
Total long-term liabilities	59,678		134,485	
COMMITMENTS AND CONTINGENCIES (Notes 7, 9 and 12)				
TOTAL LIABILITIES	5,337,769		7,125,992	
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, 12,409,631				
and				
12,398,131 shares issued, and 12,313,321 and 12,291,454 outstanding,				
respectively	496,385		495,925	
Additional paid-in capital	26,338,267		26,156,864	
Common stock held in treasury (96,310 and 106,677 shares, respectively)	(356,502)		(375,813)	
Retained earnings (accumulated deficit)	(10,088,767)		(10,436,794)	
Cumulative translation adjustment	(78,629)		12,904	
Total stockholders' equity	16,310,754		15,853,086	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 21,648,523	\$	22,979,078	

See notes to consolidated financial statements.

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS YEARS ENDED JUNE 30, 2007, 2006 AND 2005

	2007	2006	200	5
NET SALES (Notes 1, 10 and 11)	\$ 31,431,810	\$ 31,350,919	\$	26,781,627
COST OF GOODS SOLD	19,652,167	19,308,353		16,311,144
GROSS PROFIT	11,779,643	12,042,566		10,470,483
OPERATING EXPENSES:				
Sales and marketing (Note 1)	6,008,956	6,950,311		5,670,505
Research, development and engineering (Note 1)	2,374,345	2,362,512		2,620,134
Administrative (Note 9)	3,434,397	3,177,232		2,906,039
Total	11,817,698	12,490,055		11,196,678
LOSS FROM OPERATIONS	(38,055)	(447,489)		(726,195)
OTHER (EXPENSE) INCOME:				
Interest expense (Note 12)	(14,354)	(19,820)		(28,848)
Interest income	136,225	94,830		58,710
Foreign currency exchange gain (loss) (Note 1)	171,361	(108,225)		131,885
Other income (Note 14)	92,850	692,822		142,203
Total	386,082	659,607		303,950
INCOME (LOSS) BEFORE INCOME TAXES	348,027	212,118		(422,245)
INCOME TAX PROVISION (Notes 1 and 5)				
NET INCOME (LOSS)	\$ 348,027	\$ 212,118	\$	(422,245)
NET INCOME (LOSS) PER COMMON SHARE (Note 1):				
Basic and diluted	\$			