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
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended June 30, 2007

[ ] 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	39-1501563
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

20925 Crossroads Circle, Suite 100, Waukesha, Wisconsin	53186
(Address of Principal Executive Offices)	(Zip Code)

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

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

Title of Each Class	Name of Each Exchange on Which Registered
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 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 [X]

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.

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 (VitalCare™ 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.

VitalCare™ 506N3 Portable Vital Signs Monitors. 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, ComfortCuff™ noninvasive blood pressure and temperature (either FILAC FasTemp™ 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, ComfortCuff™ noninvasive blood pressure, DOX™ 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.

Poet™ Plus 8100 Vital Signs Monitors. The full-featured CSI 8100 Vital Signs Monitor provides maximum flexibility for hospital, transport and outpatient care settings. The unit's custom configurations include ECG, ComfortCuff™ noninvasive blood pressure, DOX™ digital oximetry, heart rate, temperature, respiration rate, and nurse call interface. Optional features include CO_2, CO_2/O_2 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.

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. 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.

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.

VitalView™ Central Monitoring Station. 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.

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.

Marketing and Sales

Domestic Sales. 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.

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 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.

Service, Support and Warranty. 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 (VitalCare™ 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 (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 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, 1/100th 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.