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CRITICARE SYSTEMS INC /DE/
Form 10-K
September 27, 2001

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

FORM 10-K

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

(Mark One)

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

For the fiscal year ended June 30, 2001

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 000-16061

Criticare Systems, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

39-1501563

(State or Other Jurisdiction of (I.R.S. Employer Identification No.)
Incorporation or Organization)

20925 Crossroads Circle, Waukesha, Wisconsin 53186

(Address of Principal Executive Offices) (Zip Code)

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

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

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

[COVER PAGE 1 OF 2 PAGES.]

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

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

(Title of class)

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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 the Form 10-K. []

The aggregate market value of the voting common stock held by nonaffiliates of the registrant as of August 31, 2001 was approximately \$34,866,000. Shares of voting common stock held by any executive officer or director of the Registrant and any person who beneficially owns 10% or more of the outstanding voting common stock have been excluded from this computation because such persons may be deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

On August 31, 2001, there were outstanding 10,796,224 shares of the registrant's \$.04 par value voting common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Annual Meeting of the Stockholders of the Registrant to be held November 30, 2001 are incorporated by reference into Part III of this report.

[COVER PAGE 2 OF 2 PAGES.]

PART I

Item 1. BUSINESS.

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

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

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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 9 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. 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.

Model 8100 and 8500 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 (TM) noninvasive blood pressure, DOX (TM) digital oximetry, heart rate, temperature, respiration and nurse call interface. Optional features include CO2 and CO2/O2 monitoring and an integrated
printer. The 8100 is well suited for busy departments that require basic vital signs monitoring to conscious sedation. The 8500 series of operating room monitors is used in conjunction with the 8100 series and provides automatic identification and quantification of all five approved anesthetic agents.

Model 503DX, 504, 504+, and 504DX Pulse Oximeters. Criticare's complete

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

Model 506DX and 507E Patient Monitors. The 507E series is comprised of

small, compact, portable, full-featured vital signs monitors configured to meet specific clinical needs. The 507E series is well-suited for dental and physician offices. The 507E series combines ECG, oxygen saturation and noninvasive blood pressure for a complete vital signs monitor for physician offices and hospital applications. The 507E series is an effective low-cost monitoring system for the emergency room or the recovery room. The 506DX is ideal for patient ward monitoring of noninvasive blood pressure.

Model 1100 Anesthesia Monitor. The Model 1100 monitor provides patient

monitoring for a wide variety of cardio-pulmonary parameters in an integrated system. The Model 1100 is able to monitor two ECG waveforms, noninvasive blood pressure, three types of invasive blood pressure, respiration rate, heart rate, temperature, oxygen saturation, inspired/expired oxygen, carbon dioxide and

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anesthetic gases. The Model 1100 uses the Company's proprietary disposable respiratory secretion filter system.

Model 4400 and 4500 Series Blood Pressure, Pulse Oximetry and Temperature

Combination Monitors. The 4400 series monitor was developed in conjunction with

Alaris Medical ("Alaris") and incorporates Criticare's oximetry and noninvasive blood pressure technology with Alaris's temperature technology. The 4500 series monitor incorporates Criticare's noninvasive blood pressure technology with Alaris's temperature technology. Alaris has the rights to market these products to hospitals in the United States and Canada. Criticare has rights to market these products to the alternate care market and to international markets.

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Model 602-14 POET(TM) LT Monitor. The hand-held POET LT provides small

hospitals and alternate care environments with compact, portable carbon dioxide monitoring. The POET LT series is an effective, low-cost functioning solution for these environments.

VitalView(TM) Central Monitoring Station. The VitalView central station

makes it possible for one nurse or technician to monitor numerous patients simultaneously. The VitalView can receive, display and store data from a wide variety of Criticare monitors including the 507E and MPT.

MPT(TM) Monitor. The MPT (Multiple Parameter Telemetry) monitor allows the

transmission of vital signs (ECG, blood oxygen saturation and noninvasive blood pressure) on a real time basis to a VitalView central station while the patient is ambulatory. In today's healthcare environment, hospitals benefit by moving patients from expensive critical care departments as quickly as possible to less expensive general nursing floors. MPT, because of its complete monitoring capability and its lower cost, allows the patient to be ambulatory while still being monitored for all vital signs.

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.

Water Chek/Chek-Mate Filter System. The Company's patented, disposable

Water Chek system separates a patient's respiratory secretions from a breath sample before it enters the gas monitor(s) for analysis. The Company's proprietary, disposable Chek-Mate filter enhances the removal of moisture from the sample, while preventing cross-contamination. This system allows the monitor to operate effectively regardless of humidity or patient condition. The self-sealing feature also protects the healthcare provider from potential contamination. Criticare has entered into three contracts to supply Water Chek systems to be utilized on OEM supplied equipment to the final customer.

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Marketing and Sales

Domestic Sales. At August 31, 2001, the Company's domestic sales force ----- consisted of eight employees and 100 independent dealers. The Company's sales force and independent dealers market the Company's products to many different types of medical facilities such as hospitals, surgery centers, nursing homes and physician offices. The Company sells its higher-end monitors (MPT, Vital View Central Station and

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anesthetic agent monitors) principally to hospitals whereas the vital signs and pulse oximeters are sold primarily for nonhospital settings.

The Company has begun to focus on selling to original equipment manufacturers ("OEMs"). OEM business has become a significant sales channel for the Company and is expected to be the primary driver of growth in future periods.

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 2001, Criticare sold its products, principally to hospitals, in over 75 countries through over 75 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 management.

In fiscal 2001, 41% of Criticare's net sales, or \$11.4 million, was attributable to international sales, of which approximately 60% was from sales in Europe and the Middle East, 20% was from sales to Pacific Rim countries and 20% was from sales to Canada and Central and South America. In fiscal 2000, 41% of Criticare's net sales were attributable to international sales. In fiscal 1999, 37% of Criticare's net sales were attributable to exports. There are no material identifiable assets of the Company located in foreign markets. The Company sells its products in United States dollars and is not subject to significant currency risks; 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.

Clinical Support. At August 31, 2001, Criticare employed one clinical ----- support specialist to provide customer training and education, primarily to domestic hospitals. The clinical support specialist also assists in the periodic training and education of the direct sales force. In addition, the direct sales force maintains contact with end-users and provides additional training and updates. Clinical support in foreign markets is provided by the Company's clinical support staff and direct sales force.

Warranty and Service. Criticare believes that customer service is a key ----- element of its marketing program. Criticare's monitors and sensors are warranted against defects for one year. If a problem develops with a Criticare product

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while under warranty, the Company typically provides a replacement unit until the product can be repaired at the Company's facility. At August 31, 2001, the Company had a customer service staff of 16 people at its Waukesha, Wisconsin facility. The Company offers extended warranties and service contracts on all of its monitors.

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Manufacturing

Historically, Criticare has manufactured and assembled its products internally, principally at the Company's facility in Waukesha, Wisconsin. Recently, prices for monitoring systems have eroded worldwide. In response to this pricing pressure, in fiscal 2001 the Company entered into agreements with two offshore contract manufacturing firms located in Ireland and Taiwan, respectively, that exclusively manufacture medical devices in a regulated environment. The Company has worked closely with these two firms to maintain product quality and reliability. These two firms will perform the same rigorous quality control testing at their facilities that Criticare has done in the past. The Company expects to be out of the manufacturing of substantially all of its established product lines by the end of calendar year 2001 and will then concentrate on product enhancements and new product development, customer service, and increased involvement with its OEM customers. The Company anticipates that it will continue limited production of new products internally during the development phase and for a short period after commercial introduction until production can be transitioned to the offshore manufacturers.

The Company's oximeters and sensors are assembled from off-the-shelf components and other parts produced to the Company's specifications, such as printed circuit board assemblies, custom transformers and sensor cable/connector subassemblies. Certain of Criticare's products incorporate components currently purchased from single sources. While the Company believes these components are available from alternate sources on reasonable terms, an interruption in the delivery of these or other components could have an adverse effect on the Company. In order to reduce the risk of supply interruption, the Company maintains inventories of certain components.

The ISO 9000 series of quality management and assurance standards was developed by the International Organization for Standardization (ISO) and published in 1987. In 1993 the EC (European Community) was formed with the signing of the Maastricht Treaty by 12 European countries. One of the many standards adopted by this group is the ISO 9000 international quality assurance and quality management series under the designation EN2 9000. Based on this action by the EC and specific requirements from European customers, the Company believes ISO 9000 registration will be required to compete in EC and other international markets as an indication of compliance with international quality management and assurance standards. In July 1994 the Food and Drug Administration (FDA) announced its intention of harmonizing the ISO 9000 standards with its Medical Device Good Manufacturing Practices (GMP). The Company has achieved certification under ISO's standards 9001 and 9002. Each of the offshore contract manufacturing firms has achieved certification under ISO's standard 9001. See "Regulation."

Research, Development and Engineering

Criticare has focused its research, development and engineering expenditures on products designed to meet identified market demands. The Company seeks to apply its expertise in gas monitoring and related sensor technology to develop new products and adapt existing products for new markets. At August 31,

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2001, the Company had an in-house research, development and engineering staff of 21 people. The Company's research, development and engineering expenditures were \$2.4 million in fiscal 2001, \$2.9 million in fiscal 2000 and \$3.0 million in fiscal 1999.

The Company made significant investments in engineering in 1999 and 2000 to update the entire Criticare product line and develop the 8100 vital signs monitor. In 2001, research and development efforts were more focused on refinements to the 8100 product line and the development of the 8500 series monitor which features automatic identification and quantification of all five approved anesthetic agents.

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Competition

The markets for the Company's products are highly competitive. Many of Criticare's competitors, including its principal competitors described below, have greater financial resources, more established brand identities and reputations, longer histories in the medical equipment industry and larger and more experienced sales forces than Criticare. In these respects, such competitors have a competitive advantage over the Company. 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 principal competing manufacturers of pulse oximeters are Nellcor Puritan Bennett, a unit of a subsidiary of Tyco International Ltd., and Datex/Ohmeda, a United States subsidiary of Instrumentarium OY, a Finnish company. The Company estimates that Nellcor Puritan Bennett has captured a majority of the worldwide pulse oximeter market, and that Datex/Ohmeda and the Company have each captured significant portions of the worldwide pulse oximeter market. In addition, there are approximately four other companies which compete in the market for pulse oximeters. The Company also indirectly competes with manufacturers of numerous other medical equipment products for limited customer funds.

The Company believes that the worldwide anesthetic agent and carbon dioxide monitor markets are comparatively fragmented, with Datex/Ohmeda as the principal competitor. The Company's principal competitors in the domestic gas monitor market include Datex/Ohmeda and Koninklijke Philips Electronics N.V. The market for vital signs monitors includes competitors such as Koninklijke Philips Electronics N.V., Siemens A.G., Datex/Ohmeda and Spacelabs Medical, Inc.

The Company believes that its principal competitors in Western Europe include Datex/Ohmeda and that the Company has a significant share of this market. In the Pacific Rim countries, the Company believes that Datex/Ohmeda is the leading competitor.

Regulation

As a manufacturer of medical diagnostic equipment, the Company is regulated by the FDA and similar foreign governmental agencies. In producing its

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products, the Company must comply with a variety of regulations, including the good manufacturing practices regulations of the FDA. In addition, it is subject to periodic inspections by this

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agency. If the FDA believes that its legal requirements have not been fulfilled, it has extensive enforcement powers, including the ability to ban or recall products from the market and to prohibit the operation of manufacturing facilities. The Company believes its products comply with applicable FDA regulations in all material respects. In addition, the Company received ISO 9002 certification on April 29, 1993 and ISO 9001 certification on July 8, 1994.

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

The Company's current products have not been subject to the FDA's comprehensive premarket approval requirements, but are generally subject to premarket notification requirements. If a new device is substantially equivalent to a device that did not require premarket approval, premarket review is satisfied through a procedure known as a "510(k) submission," under which the applicant provides product information supporting its claim of substantial equivalence. The FDA may also require that it be provided with clinical trial results showing the device's safety and efficacy.

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

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

Patents and Trademarks

The Company believes one of its principal competitive advantages is provided by its patented and other proprietary technology including its sensor technology, infrared specific anesthetic gas monitoring technology, UltraSync signal processing software and disposable respiratory secretion filter system. The Company has 13 issued U.S. patents and three patent applications pending. The Company's U.S. patents expire between 2004 and 2015. Criticare also has two issued foreign patents and 11 foreign patent applications pending. There is no assurance that any patents held or secured by the Company will provide any protection or

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commercial or competitive benefit to the Company. There is also no assurance that the Company's products will not infringe upon patents held by others. The Company is the owner of United States trademark registrations for "POET," "MPT," "REMOTEVIEW" and "MICROVIEW."

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The Company also relies upon trade secret protection for certain of its proprietary technology. Although the Company requires its employees having access to its proprietary information 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, 2001 Criticare had 86 employees; including 31 in manufacturing and operations, five in quality control, 16 in sales and marketing, 13 in administration and 21 in research, development and engineering.

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, 2001 and 2000 was approximately \$813,000 and \$1,833,000, respectively. The backlog at June 30, 2000 was significantly higher than the current year due to problems experienced in obtaining components from suppliers in fiscal 2000. This prevented the Company from shipping products where orders had been received, and increased the backlog in fiscal 2000.

Criticare generally delivers its products out of inventory when specified by the customer. The Company does not believe that its backlog at any date is indicative of its future sales.

Item 2. PROPERTIES.

In November 1992, the Company purchased a new 60,000 square foot facility for approximately \$4.5 million. The Company's mortgage calls for monthly installments of principal and interest of approximately \$28,000 and a final "balloon" payment of approximately \$3.0 million in April 2004. Due mainly to the Company's outsourcing initiatives, there is currently excess capacity available at this facility. The Company is evaluating alternatives in order to eliminate this excess capacity and reduce costs, including the potential sale of the facility or the leasing of a portion of the facility.

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

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claim or action the ultimate disposition of which would have a material adverse effect on Criticare.

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

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No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended June 30, 2001.

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PART II

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

MATTERS.

The Company's common stock is traded on the Nasdaq National Market (Symbol CXIM). As of June 30, 2001, there were approximately 257 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.

| | Year Ended June 30, | | | |
|--------------------------|---------------------|---------|---------|---------|
| | 2001 | | 2000 | |
| | ----- | ----- | ----- | ----- |
| Quarter Ended:.. | High | Low | High | Low |
| September 30. | \$ 3.38 | \$ 2.31 | \$ 2.88 | \$ 1.88 |
| December 31 (1). | \$ 3.00 | \$ 1.63 | \$ 2.75 | \$ 2.00 |
| March 31. | \$ 3.44 | \$ 1.94 | \$ 5.06 | \$ 2.25 |
| June 30 | \$ 4.49 | \$ 2.55 | \$ 3.44 | \$ 1.97 |

(1) Trading of the Company's common stock on the Nasdaq National Market was suspended from October 6, 1999 until December 13, 1999 due to the delayed filing of the Company's 1999 Annual Report on Form 10-K with the SEC.

Item 6. SELECTED FINANCIAL DATA.

The following table sets forth selected financial data with respect to the Company for each of the periods indicated.

| | Years Ended June 30, | | | | |
|---|----------------------|--------------|--------------|--------------|--------------|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | ----- | ----- | ----- | ----- | ----- |
| Net sales. | \$27,736,304 | \$27,154,236 | \$28,512,507 | \$27,908,364 | \$26,235,300 |
| Loss before income taxes and extraordinary gain | (178,232) | (186,388) | (4,388,171) | (499,276) | (2,749,480) |
| Net loss | (178,232) | (186,388) | (4,388,171) | (499,276) | (2,179,480) |
| Net loss per common share- | | | | | |
| basic and diluted. | \$ (0.02) | \$ (0.02) | \$ (0.51) | \$ (0.06) | \$ (0.30) |
| Average shares outstanding | 10,171,394 | 8,694,918 | 8,581,863 | 8,309,240 | 7,267,100 |
| Stockholders' equity | \$21,005,816 | \$18,798,952 | \$12,711,709 | \$17,282,997 | \$14,227,100 |
| Long-term obligations. | 3,270,140 | 3,552,474 | 4,014,356 | 3,165,258 | 5,110,900 |
| Working capital. | 17,995,497 | 16,257,780 | 10,340,014 | 13,716,891 | 12,053,100 |

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Total assets 29,871,854 27,210,867 24,041,987 24,726,819 25,145,0

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

 RESULTS OF OPERATION.

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, | | |
| | ----- | | |
| | 2001 | 2000 | 1999 |
| | ----- | | |
| Net sales | 100.0% | 100.0% | 100.0% |
| Cost of goods sold. | 59.4 | 60.6 | 54.5 |
| Gross profit. | 40.6 | 39.4 | 45.5 |
| Operating expenses: | | | |
| Marketing | 23.0 | 29.5 | 31.4 |
| Research, development and engineering | 8.8 | 10.5 | 10.4 |
| Administrative. | 9.1 | 8.6 | 14.6 |
| Severance pay | -- | -- | 2.8 |
| Total | 40.9 | 48.6 | 59.2 |
| (Loss) from operations. | (0.3) | (9.2) | (13.7) |
| Interest expense. | (0.9) | (1.0) | (1.5) |
| Interest income | 0.5 | 0.3 | 0.3 |
| Equity in loss of investments | -- | -- | (0.5) |
| Gain on sale of stock | -- | 9.2 | -- |
| Loss before income taxes. | (0.7) | (0.7) | (15.4) |
| Income tax provision. | -- | -- | -- |
| Net loss. | (0.7)% | (0.7)% | (15.4)% |

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FISCAL YEAR ENDED JUNE 30, 2001 COMPARED TO JUNE 30, 2000

Net sales for the fiscal year ended June 30, 2001 increased 2% from the prior year. However, two significant and isolated sales in the prior year, combined with the partial return of product from one of these sales in the current year, had the effect of increasing prior year revenue and reducing current year revenue. Adjusting for these items, the net sales in fiscal 2001 increased over \$2.6 million, or 10.3%, above the prior year. Approximately \$2.1 million of this increase can be attributed to higher OEM sales, which grew 73% from the prior year on a 77% increase in the number of units shipped. OEM business has become a significant distribution channel in fiscal 2001, and this trend towards OEM contributing more to overall Company sales is expected to continue in fiscal

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2002 and future years. Higher replacement part shipments contributed another \$300,000 to the sales increase between years.

The gross profit percentage of 40.6% realized in fiscal 2001 improved from the 39.4% generated in fiscal 2000. Margins in the current year were favorably impacted by the recognition of \$105,000 in deferred income from the settlement of a contract that was agreed to in January 2000 and fully satisfied in the third quarter of fiscal 2001. In addition, a warranty reserve was reduced by \$105,000 due to favorable warranty experience on extended warranty contracts sold to customers, and a reserve for obsolete inventory was decreased by \$75,000. These adjustments increased margins approximately 1.0 percentage point in fiscal 2001. The Company expects to see improvement in its margins in fiscal 2002 due to lower product costs expected from outsourcing the manufacturing of the majority of its product lines to foreign manufacturers. See "Forward-Looking Statements."

Total operating expenses were \$1,856,000 lower in fiscal 2001 than the prior year, of which \$1.2 million of this reduction was due to a decrease in bad debt expense between years. Marketing expenses in fiscal 2000 included bad debt expense of \$1.2 million, including a specific charge of \$900,000 in the fourth quarter related to the receivable balances of certain international customers that were deemed to be uncollectible during the fourth quarter. Marketing expenses in fiscal 2001 included a \$300,000 recovery of a portion of the bad debt expense recognized in the fourth quarter of the prior year from the repossession of inventory sold, and more than offset the bad debt provision provided in fiscal 2001. Excluding the \$1.2 million impact on bad debt expense between years, marketing expenses were still down \$447,000 in fiscal 2001, due mainly to more cost-effective spending on travel and trade shows. In addition to the reduction in marketing expenses, engineering project expenses were reduced nearly \$500,000 in fiscal 2001, due to significant spending incurred in fiscal 2000 related to the development of the 8100 product that was released in late fiscal 2000. The reduction in marketing and engineering expenses more than offset the \$200,000 increase in administrative expenses related mostly to the termination and replacement of a senior manager in fiscal 2001.

The overall \$1,856,000 reduction in operating expenses in fiscal 2001, combined with slightly higher revenue and improved margins compared to the prior year, resulted in an \$86,000 loss from operations, which represented a significant improvement from the \$2,518,000 operating loss generated in fiscal 2000.

Other income and expense in fiscal 2001 is comparable to that of the prior year with the exception of the \$2.5 million gain recorded in fiscal 2000. This gain related to the private placement sale of a portion of the Company's stock investment in Immtech International, Inc., in which the Company still has a position. The large gain allowed the Company to offset the majority of the operating loss produced in fiscal 2000, resulting in a net loss of \$186,000, that was \$8,000 greater than the \$178,000 loss generated in fiscal 2001.

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FISCAL YEAR ENDED JUNE 30, 2000 COMPARED TO JUNE 30, 1999

For the twelve months ended June 30, 2000, international sales rose approximately \$600,000, but were offset by a decrease in total domestic sales of approximately \$2,000,000. The increase in international sales was driven by a 13% increase in the number of units sold and was partially offset by a 4% decrease in the average sales price per unit. The reduction in domestic sales was due to both lower volume, as the number of units shipped fell 15%, and a 7% decrease in the average sales price between years. The net result was a decline in net sales of 4.8%, from \$28,512,507 to \$27,154,236.

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The gross profit percentage declined from 45.5% in 1999 to 39.4% in 2000. This decrease is due primarily to continued price erosion on products in a portion of the Company's older product line.

Total operating expenses were reduced by \$3,700,000, which represents a 21.7% cost reduction during fiscal 2000. Marketing expenses were lowered by approximately \$900,000 due to a variety of factors. These include a reduction in service labor and materials, a decrease in payroll and related travel expenses due to a reduction in direct sales people as more dealers were added, and a decrease in commissions associated with the lower sales. Offsetting the \$1,800,000 of reductions was a \$900,000 increase in the reserve for doubtful accounts related to the receivable balances of certain international customers. Research and development expenses decreased approximately \$100,000, as the design phase of the 8100 product was completed and production commenced. Administration expenses decreased approximately \$2,000,000. The majority of this reduction is due to the non-reoccurring litigation and settlement costs associated with a lawsuit in the prior year. In addition, \$810,000 of severance costs were recorded in 1999.

Interest expense was reduced \$170,000 from 1999 levels due to the mortgage that was refinanced in March 1999. However, the more significant change is the \$2,500,000 gain recorded on the private placement sale of 500,000 Immtech shares in fiscal 2000.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2001, the Company had a cash balance of approximately \$3.4 million and no short-term borrowings. In October 2000, the Company received \$4.0 million in proceeds from a private placement of additional shares of the Company's common stock. These proceeds allowed the Company to increase its cash balance in fiscal 2001 almost \$3.3 million from the prior year. In fiscal 2001, the Company used \$688,322 of these proceeds for capital expenditures, \$80,433 to retire long-term debt, and \$73,807 to fund operations.

In fiscal 2000, the Company generated negative cash flow of \$2,396,248 due mainly to payments made in fiscal 2000 to either partially or fully satisfy liabilities accrued at the end of fiscal 1999. Accrued liabilities in fiscal 2000 were reduced \$2,400,344 due mostly to a \$1,600,000 payment to a former dealer for the settlement of a lawsuit, the recognition of \$380,000 of deferred income as revenue from a large customer deposit received late in fiscal 1999, and the payment of approximately \$350,000 of severance to the two co-founders of the Company who resigned from their positions in fiscal 1999. These items, all accrued in fiscal 1999 and partially or fully settled or realized in fiscal 2000, decreased accrued liabilities and cash flow in fiscal 2000 and increased accrued liabilities and cash flow in fiscal 1999. A \$1,349,278 increase in accounts receivable also reduced cash flow in fiscal 2000. Higher sales of \$1,207,740 in the last two months of fiscal 2000 compared to the prior year, the majority of which were not yet due and therefore not collected before the end of June, increased the accounts receivable balance and decreased cash flow between years.

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In March 1999, the Company refinanced its mortgage note on the Company's office and manufacturing facility. The new mortgage note requires monthly debt service payments of approximately \$28,000, with a final payment of approximately \$3,000,000 due in April 2004.

The Company has implemented programs to increase accounts receivable

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collections, decrease inventory levels, reduce product development tooling requirements, and lower sales demonstration equipment levels in order to improve cash flow in the next fiscal year. Therefore, the Company expects that its research and development activities and other capital and liquidity requirements for the next twelve months will be satisfied by cash generated from operations and its current cash balances. There are currently no significant capital expenditures planned for fiscal 2002. During fiscal 2001, the Company also had access to a commercial bank demand line of credit of up to \$4,000,000. At June 30, 2001, there were no borrowings outstanding on the line of credit. The Company violated a covenant related to achieving certain income levels. The bank waived compliance with this covenant subsequent to year end. This line expires in November 2001, but is expected to be extended with terms consistent with the current agreement.

FORWARD-LOOKING STATEMENTS

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

The Company's business, operations and financial performance are subject to certain risks and uncertainties which could result in material differences in actual results from management's or the Company's current expectations. These risks and uncertainties include, but are not limited to, general economic conditions, demand for the Company's products, costs of operations, the development of new products, the reliance on single sources of supply for certain components in the Company's products, government regulation, health care cost containment programs, the effectiveness of the Company's programs to manage working capital and reduce costs, competition in the Company's markets, unanticipated difficulties in outsourcing the manufacturing of the majority of its products to foreign manufacturers and risks related to foreign manufacturing, including economic and political instability, trade and foreign tax laws, production delays and cost overruns and quality control, and the Company's ability to reduce costs by eliminating excess capacity at its principal facility.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company has a 7.5% fixed rate mortgage note outstanding on its facility and land. In addition, the Company has a demand line of credit facility with a commercial bank with interest payable monthly at 25 basis points above the bank's reference rate. The Company had no borrowings outstanding under this bank facility at June 30, 2001, 2000, and 1999. The Company could be subject to financial risk on these two obligations if interest rates in the market change significantly.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

FINANCIAL STATEMENTS

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CONSOLIDATED BALANCE SHEETS
JUNE 30, 2001 AND 2000

| ASSETS | 2001 | 2000 |
|---|--------------|--------------|
| | ----- | ----- |
| CURRENT ASSETS: | | |
| Cash and cash equivalents (Note 1) | \$ 3,362,104 | \$ 114,830 |
| Accounts receivable, less allowance for doubtful accounts of \$1,000,000 and \$1,300,000, respectively | 7,122,464 | 6,782,765 |
| Investments (Notes 1 and 3) | 3,970,454 | 5,704,675 |
| Other receivables | 33,788 | 116,773 |
| Inventories (Notes 1 and 2) | 8,600,413 | 8,178,326 |
| Prepaid expenses | 502,172 | 219,852 |
| | ----- | ----- |
| Total current assets | 23,591,395 | 21,117,221 |
| PROPERTY, PLANT AND EQUIPMENT (Notes 1 and 5): | | |
| Land | 925,000 | 925,000 |
| Building | 3,600,000 | 3,600,000 |
| Machinery and equipment | 2,055,518 | 2,009,312 |
| Furniture and fixtures | 837,238 | 763,282 |
| Demonstration and loaner monitors | 1,463,909 | 1,407,587 |
| Production tooling | 3,122,938 | 2,651,145 |
| | ----- | ----- |
| Property, plant and equipment - cost | 12,004,603 | 11,356,326 |
| Less accumulated depreciation | 5,822,133 | 5,367,670 |
| | ----- | ----- |
| Property, plant and equipment - net | 6,182,470 | 5,988,656 |
| OTHER ASSETS (Note 1): | | |
| License rights and patents - net | 97,989 | 104,990 |
| | ----- | ----- |
| Total other assets | 97,989 | 104,990 |
| | ----- | ----- |
| TOTAL | \$29,871,854 | \$27,210,867 |
| | ===== | ===== |

See notes to consolidated financial statements.

| LIABILITIES AND STOCKHOLDERS' EQUITY | 2001 | 2000 |
|---|--------------|--------------|
| | ----- | ----- |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 3,421,776 | \$ 2,635,340 |
| Accrued liabilities: | | |
| Compensation and commissions | 1,187,493 | 1,243,830 |
| Product warranties (Note 1) | 220,000 | 325,000 |
| Accrued taxes other than income | 96,947 | 126,760 |
| Accrued audit and legal fees | 35,900 | 20,000 |
| Other | 547,025 | 428,050 |
| Current maturities of long-term debt (Note 5) | 86,766 | 80,430 |
| | ----- | ----- |

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| | | |
|---|--------------|-------------|
| Total current liabilities | 5,595,907 | 4,859,44 |
| LONG-TERM DEBT, less current maturities (Note 5) | 3,197,126 | 3,283,89 |
| OTHER LONG-TERM OBLIGATIONS (Note 12) | 73,005 | 268,58 |
| CONTINGENCIES (Note 6) | | |
| STOCKHOLDERS' EQUITY (Notes 5 and 7): | | |
| Preferred stock - \$.04 par value, 500,000 shares authorized, no shares issued or outstanding | -- | -- |
| Common stock - \$.04 par value, 15,000,000 shares authorized, 10,796,224 and 8,976,251 shares issued and outstanding, respectively | 431,849 | 359,05 |
| Additional paid-in capital | 22,494,548 | 18,478,04 |
| Common stock held in treasury (64,134 and 81,122 shares, respectively). | (119,467) | (151,11 |
| Retained earnings (accumulated deficit) | (5,771,568) | (5,591,70 |
| Accumulated comprehensive income. | 3,970,454 | 5,704,67 |
| Total stockholders' equity. | 21,005,816 | 18,798,95 |
| TOTAL | \$29,871,854 | \$27,210,86 |
| | ===== | ===== |

See notes to consolidated financial statements.

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED JUNE 30, 2001, 2000 AND 1999

| | 2001 | 2000 | 1999 |
|--|--------------|--------------|--------------|
| | ----- | ----- | ----- |
| NET SALES (NOTE 9) | \$27,736,304 | \$27,154,236 | \$28,512,507 |
| COST OF GOODS SOLD | 16,469,119 | 16,462,477 | 15,528,314 |
| GROSS PROFIT | 11,267,185 | 10,691,759 | 12,984,193 |
| OPERATING EXPENSES: | | | |
| Marketing (Note 1) | 6,367,395 | 8,014,129 | 8,941,036 |
| Research, development and engineering (Note 6) | 2,446,907 | 2,861,733 | 2,963,134 |
| Administrative (Note 6) | 2,538,938 | 2,333,445 | 4,157,811 |
| Severance pay (Note 12) | -- | -- | 810,000 |
| Total. | 11,353,240 | 13,209,307 | 16,871,981 |
| LOSS FROM OPERATIONS | (86,055) | (2,517,548) | (3,887,788) |
| OTHER INCOME (EXPENSE): | | | |
| Interest expense (Note 5) | (253,150) | (259,280) | (427,008) |
| Interest income. | 157,782 | 90,440 | 82,094 |
| Equity in loss of investments (Notes 1 and 3). | -- | -- | (150,000) |
| Gain on sale of stock (Note 3) | -- | 2,500,000 | -- |
| Other income/(expense) | 3,191 | -- | (5,469) |
| Total. | (92,177) | 2,331,160 | (500,383) |

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| | | | |
|---|--------------|--------------|----------------|
| LOSS BEFORE INCOME TAXES | (178,232) | (186,388) | (4,388,171) |
| INCOME TAX PROVISION (NOTES 1 AND 4) | --- | --- | --- |
| | ----- | ----- | ----- |
| NET LOSS | \$ (178,232) | \$ (186,388) | \$ (4,388,171) |
| | ===== | ===== | ===== |
| NET LOSS PER COMMON SHARE: | | | |
| Basic. | \$ (0.02) | \$ (0.02) | \$ (0.51) |
| Diluted. | \$ (0.02) | \$ (0.02) | \$ (0.51) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING (NOTE 7): | | | |
| Basic. | 10,171,394 | 8,694,918 | 8,581,863 |
| Diluted. | 10,171,394 | 8,694,918 | 8,581,863 |

See notes to consolidated financial statements.

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CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED JUNE 30, 2001, 2000 AND 1999

| | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Common Stock Treasury Shares | Treasury Cost | |
|---|------------------------|------------------------|----------------------------------|------------------------------------|------------------|-------|
| BALANCE, JUNE 30, 1998. | 8,351,151 | \$334,046 | \$17,964,250 | | | \$ (1 |
| Net loss. | | | | | | (4 |
| Comprehensive income/(loss) | | | | | | |
| Issuance of common stock for patented technology | 350,000 | 14,000 | (14,000) | | | |
| Exercise of options and warrants. | 5,000 | 200 | 10,113 | | | |
| Common stock repurchased. | | | | 103,840 | (193,430) | |
| BALANCE, JUNE 30, 1999. | 8,706,151 | 348,246 | 17,960,363 | 103,840 | (193,430) | (5 |
| Net loss. | | | | | | |
| Unrealized gain on investment | | | | | | |
| Comprehensive income/(loss) | | | | | | |
| Common stock issued in settlement of lawsuit. | 30,000 | 1,200 | 68,175 | | | |
| Exercise of options | 240,100 | 9,604 | 448,746 | | | |
| Employee common stock purchased from treasury | | | 756 | (22,718) | 42,319 | |
| BALANCE, JUNE 30, 2000. | 8,976,251 | 359,050 | 18,478,040 | 81,122 | (151,111) | (5 |
| Net loss. | | | | | | |
| Unrealized (loss) on investment | | | | | | |
| Comprehensive income/(loss) | | | | | | |
| Common stock issued | 1,801,273 | 72,051 | 3,977,063 | | | |
| Exercise of options | 18,700 | 748 | 2,273 | | | |
| Employee common stock | | | | | | |

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| | | | | | | |
|---|----------------------------------|-----------|--------------|----------|--------------|-------|
| purchased from treasury | | | 37,172 | (16,988) | 31,644 | |
| BALANCE, JUNE 30, 2001. | 10,796,224 | \$431,849 | \$22,494,548 | 64,134 | \$ (119,467) | \$ (5 |
| | Total Stockholders' Equity | | | | | |
| BALANCE, JUNE 30, 1998. | \$17,282,997 | | | | | |
| Net loss. | (4,388,171) | | | | | |
| Comprehensive income/(loss) | (4,388,171) | | | | | |
| Issuance of common stock for patented technology | - | | | | | |
| Exercise of options and warrants. | 10,313 | | | | | |
| Common stock repurchased. | (193,430) | | | | | |
| BALANCE, JUNE 30, 1999. | 12,711,709 | | | | | |
| Net loss. | (186,388) | | | | | |
| Unrealized gain on investment | 5,704,675 | | | | | |
| Comprehensive income/loss | 5,518,287 | | | | | |
| Common stock issued | 69,375 | | | | | |
| Exercise of options | 458,350 | | | | | |
| Employee common stock purchased from treasury | 41,231 | | | | | |
| BALANCE, JUNE 30, 2000. | 18,798,952 | | | | | |
| Net loss. | (178,232) | | | | | |
| Unrealized (loss) on investment | (1,734,221) | | | | | |
| Comprehensive income/loss | (1,912,453) | | | | | |
| Common stock issued | 4,049,114 | | | | | |
| Exercise of options | 3,021 | | | | | |
| Employee common stock purchased from treasury | 67,182 | | | | | |
| BALANCE, JUNE 30, 2001. | \$21,005,816 | | | | | |

See notes to consolidated financial statements.

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED JUNE 30, 2001, 2000 AND 1999

| | 2001 | 2000 | 1999 |
|--|--------------|--------------|-------|
| | ----- | ----- | ----- |
| OPERATING ACTIVITIES: | | | |
| Net loss | \$ (178,232) | \$ (186,388) | \$ (4 |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | | |
| Depreciation | 742,931 | 871,510 | |
| Amortization | 7,001 | 7,001 | |
| Provision for doubtful accounts. | (300,000) | 925,000 | |
| Gain on sale of Immtech stock. | -- | (2,500,000) | |
| Litigation settled with common stock | -- | 69,375 | |
| Changes in assets and liabilities: | | | |

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| | | | |
|--|--------------|-------------|------|
| Accounts receivable. | (39,699) | (1,349,278) | |
| Other receivables. | 82,985 | (33,667) | |
| Inventories. | (670,510) | 341,955 | |
| Prepaid expenses | (282,320) | (27,562) | |
| Accounts payable | 786,432 | (442,676) | |
| Accrued liabilities. | (251,877) | (2,401,762) | 2, |
| | ----- | ----- | |
| Net cash (used in) provided by operating activities. | (103,289) | (4,726,492) | |
| INVESTING ACTIVITIES: | | | |
| Purchases of property, plant and equipment, net. | (688,322) | (595,412) | |
| Proceeds from sale of Immtech stock. | -- | 2,500,000 | |
| | ----- | ----- | |
| Net cash (used in) provided by investing activities. | (688,322) | 1,904,588 | |
| FINANCING ACTIVITIES: | | | |
| Net proceeds from mortgage refinancing | -- | -- | |
| Repurchase of Company stock. | -- | -- | |
| Principal payments on long-term debt | (80,432) | (73,925) | |
| Proceeds from issuance of common stock | 4,119,317 | 499,581 | |
| | ----- | ----- | |
| Net cash provided by (used in) financing activities. | 4,038,885 | 425,656 | |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 3,247,274 | (2,396,248) | |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR | 114,830 | 2,511,078 | 2, |
| CASH AND CASH EQUIVALENTS, END OF YEAR | \$ 3,362,104 | \$ 114,830 | \$2, |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | | |
| Cash paid for: | | | |
| Income taxes paid-net. | \$ 16,639 | \$ 7,535 | \$ |
| Interest | 253,653 | 259,590 | |
| Noncash investing and financing activities: | | | |
| Litigation settled with common stock | -- | 69,375 | |
| Cost of fixed asset disposals. | -- | 201,072 | |
| Unrealized (loss)/gain on investment in Immtech. | (1,734,221) | 5,704,675 | |

See notes to consolidated financial statements.

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NOTES TO FINANCIAL STATEMENTS

CRITICARE SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
 YEARS ENDED JUNE 30, 2001, 2000 AND 1999

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF BUSINESS - Criticare Systems Inc. designs, manufactures and markets patient monitoring equipment and related accessories to the health care community worldwide and is headquartered in Waukesha, Wisconsin. The Company sells domestically primarily to oral and stand-alone general surgery centers and hospitals through regional sales managers and a dealer network. Internationally, the Company sells mainly to hospitals through country managers and a worldwide dealer network.

PRINCIPLES OF CONSOLIDATION - The consolidated financial statements include the accounts of Criticare Systems, Inc. (the "Company") and its wholly owned subsidiaries: Criticare International GmbH Marketing Services ("Criticare International"), CSI Trading, Inc. ("CSI Trading"), Criticare Service GmbH,

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Criticare Biomedical, Inc. ("Criticare Biomedical"), Sleep Care, Inc. ("Sleep Care"), Criticare (FSC), Inc. and CSI International Corp. (DISC). CSI Trading was incorporated in November 1996 to assist with European marketing activities and includes a branch sales office in India. All significant intercompany accounts and transactions have been eliminated.

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

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

INVESTMENTS - In fiscal 2000, the Company ceased accounting for its investment in Immtech International, Inc ("Immtech") under the equity method and recorded the asset on the balance sheet at its fair market value in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (see Note 3).

PROPERTY, PLANT AND EQUIPMENT - Property, plant and equipment is recorded at cost. Each member of the Company's sales force is provided with demonstration monitors to assist them in their sales efforts. Also, the Company has loaner monitors which are used to temporarily replace a customer's unit when it is being repaired or upgraded. Depreciation is provided over the estimated useful lives of the assets. The building is being depreciated over 40 years, and the remaining assets are being depreciated over three to seven years, using primarily the straight-line method.

LICENSE RIGHTS AND PATENTS - License rights and patents are amortized over the estimated useful lives of the related agreements using primarily the straight-line method. Approximately \$7,000 of amortization was charged to operations in each of

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the fiscal years ended June 30, 2001, 2000 and 1999. Accumulated amortization approximated \$99,000 and \$92,000 at June 30, 2001 and 2000, respectively.

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

PRODUCT WARRANTIES - Estimated costs for product warranties are accrued for and charged to operations as the related products are shipped.

MARKETING EXPENSES - Marketing expenses include all of the Company's sales related costs. In fiscal 2001, recoveries of bad debts expensed in prior years more than offset additional provisions expensed in the current year, resulting in a net credit of bad debt expense of \$(25,757). The amount incurred in fiscal 2000 includes a \$900,000 charge to bad debt expense related to the accounts receivable balances of certain international customers. Bad debt expense totaled \$1,160,614 and \$380,004 for the years ended June 30, 2000 and 1999, respectively.

RESEARCH AND DEVELOPMENT EXPENSES - Research and development costs are charged to operations as incurred. Such expenses approximated \$2,325,000, \$2,696,000 and \$2,798,000 in 2001, 2000 and 1999, respectively.

INCOME TAXES - The Company accounts for income taxes using an asset and liability approach. Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future

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based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income.

NET INCOME (LOSS) PER COMMON SHARE - Basic income (loss) per share is computed using the weighted average number of common shares outstanding during the periods. Diluted income per share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. The basic and diluted weighted average number of common shares outstanding in the financial statements are the same because including a diluted calculation in a loss position would produce an anti-dilutive per share amount. The number of diluted weighted average common shares outstanding would be higher by 370,260 shares in 2001 and 236,024 shares in 2000 without this anti-dilutive impact.

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

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

APPROVED ACCOUNTING STANDARDS - In June 2001, the Financial Accounting Standards Board finalized FASB Statements No. 141, "Business Combinations" (SFAS 141), and No. 142, "Goodwill and Other Intangible Assets" (SFAS 142). SFAS 141 requires the use of the purchase method of accounting and prohibits the use of the pooling-of-interests method of accounting for business combinations initiated after June 30, 2001. SFAS 141 also requires that the Company recognize acquired intangible assets apart from goodwill if the acquired intangible assets meet certain criteria. SFAS 141 applies to all business combinations initiated after June 30, 2001 and for purchase business combinations completed on or after July 1, 2001. It also requires, upon adoption of SFAS 142, that the Company reclassify the carrying amounts of intangible assets and goodwill based on the criteria in SFAS 141.

SFAS 142 requires, among other things, that companies no longer amortize goodwill, but instead test goodwill for impairment at least annually. In addition, SFAS 142 requires that the Company identify reporting units for the purpose of assessing potential future impairments of goodwill, reassess the useful lives of other existing recognized intangible assets, and cease amortization of intangible assets with an indefinite useful life. An intangible asset with an indefinite useful life should be tested for impairment in accordance with the guidance in SFAS 142. SFAS 142 is required to be applied in fiscal years beginning after December 15, 2001 to all goodwill and other intangible assets recognized at that date, regardless of when those assets were initially recognized. SFAS 142 requires the Company to complete a transitional goodwill impairment test six months from the date of adoption. The Company is also required to reassess the useful lives of other intangible assets within the first interim quarter after adoption of SFAS 142.

The Company does not have any goodwill recorded as an asset as of June 30, 2001 and has only a small investment in intangible assets at June 30, 2001.

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Therefore, the Company does not expect adoption of SFAS 141 and 142 to have a material effect on the Company's financial statements.

Statement of Financial Accounting Standards No. 133 "Accounting for Derivative Instruments and Hedging Activities" (SFAS No.133) issued by the FASB is effective for financial statements with fiscal quarters of fiscal years beginning after June 15, 2000. SFAS 133 requires companies to recognize all derivative contracts as either assets or liabilities in the balance sheet and to measure them at fair value. If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (i) the changes in the fair value of the hedged asset or liability that are attributable to the hedged risk or (ii) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change.

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Historically, the Company has not entered into derivative contracts either to hedge existing risks or for speculative purposes. Accordingly, the Company does not expect adoption of the new standard to affect its financial statements.

In March 2000, the FASB issued FASB interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" ("FIN 44") which is effective July 1, 2000. This interpretation clarifies the application of APB Opinion 25 for certain issues related to stock issued to employees. The Company believes its existing stock based compensation policies and procedures are in compliance with FIN 44 and, therefore, that the adoption of FIN 44 will not have a material effect on the Company's financial statements.

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

RECLASSIFICATIONS - Certain amounts from the fiscal 2000 financial statements have been reclassified to conform to the fiscal 2001 presentation.

2. INVENTORIES

Inventories consist of the following as of June 30:

| | 2001 | 2000 |
|--------------------------------|-------------|-------------|
| Component parts | \$3,784,491 | \$3,721,474 |
| Work in process | 1,372,587 | 1,169,609 |
| Finished units. | 3,768,335 | 3,687,243 |
| | ----- | ----- |
| Total inventories | 8,925,413 | 8,578,326 |
| Less: reserve for obsolescence | 325,000 | 400,000 |
| | ----- | ----- |
| Net inventory | \$8,600,413 | \$8,178,326 |

3. INVESTMENTS

IMMTECH INTERNATIONAL, INC. - The Company owns common stock of Immtech

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International, Inc. ("Immtech"). Immtech is a biopharmaceutical company focusing on the discovery and commercialization of therapeutics for treatment of patients afflicted with opportunistic infectious diseases, cancer or comprised immune systems. Immtech has two independent programs for developing drugs: one based on a technology for the design of a class of pharmaceutical compounds referred to as dications. The second is based on developing a series of biological proteins that work in conjunction with the immune system. Immtech has no products currently for sale, and none are expected to be commercially available for several years. Immtech has a March 31 fiscal year end.

During the first and second quarters of fiscal 2000, the Company sold a portion of its Immtech stock in a Private Placement. The proceeds from this sale were \$2,500,000. As a result of this sale, the Company owns less than 20% of Immtech's issued and outstanding common stock as of June 30, 2000. Therefore, beginning in fiscal 2000, in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," the Company ceased accounting for the Immtech investment under the equity method and recorded the

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asset on the balance sheet at the fair market value of \$5,704,675. An unrealized gain was also recorded as a component of stockholders' equity. The Company held 456,374 shares of Immtech common stock, which was trading at \$8.70 and \$12.50 per share, on June 30, 2001 and 2000, respectively.

The following is a summary of the Company's investment in and advances to Immtech as of June 30, 1999:

| | 1999 |
|-----------------------------------|--------------|
| Investment in Immtech | \$ 2,736,000 |
| Advances to Immtech | 863,940 |
| | ----- |
| Total | 3,599,940 |
| Less investment losses recognized | (3,599,940) |
| | ----- |
| Net investment. | \$ 0 |

During July 1998, the Company purchased certain intangible assets and an additional 172,414 shares of Immtech stock for \$150,000. These intangibles and shares of stock were subsequently sold to the former President and Chief Executive Officer of the Company as part of a severance agreement for \$150,000 (see Note 12). At the time of this transaction, the shares of Immtech stock were carried at zero value under the equity method of accounting.

The Company has recognized investment losses related to the investment in Immtech of \$150,000 in 1999.

During April 1999, Immtech completed an Initial Public Offering ("IPO") of its stock. As part of this IPO, the Company was required to sign a lock-up agreement by which it was agreed that no shares owned by the Company could be sold in the public market until the Immtech stock traded at \$20 (200% of its initial IPO price of \$10) for 20 consecutive trading days and one year had passed from the date of the IPO. As of June 30, 2000, these lock up provisions have been satisfied.

The following is summarized financial information for Immtech at June 30, 1999 and for the twelve months then ended.

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1999

| | |
|--|--------------|
| Current assets | \$ 8,541,000 |
| Noncurrent assets | 68,000 |
| Current liabilities | 253,000 |
| Noncurrent liabilities | -- |
| Redeemable preferred stock | -- |
| Common stockholders' equity (deficit) | 8,356,000 |
| Revenues | 136,000 |
| Net loss | (8,341,000) |
| Net loss attributable to common stockholders | (4,657,000) |

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4. INCOME TAXES

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

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

| | JUNE 30, 2001 | JUNE 30, 2000 | JUNE 30, 1999 |
|---|------------------|------------------|------------------|
| Deferred income tax assets: | | | |
| Accounts receivable and sales allowances | \$ 415,000 | \$ 533,000 | \$ 170,000 |
| Inventory allowances | 164,000 | 191,000 | 254,000 |
| Product warranties | 86,000 | 128,000 | 128,000 |
| Other accrued liabilities | 210,000 | 246,000 | 392,000 |
| Severance pay accrual | 52,000 | 145,000 | 279,000 |
| Lawsuit settlement | -- | -- | 626,000 |
| Federal net operating loss carryforwards | 3,665,000 | 3,320,000 | 2,014,000 |
| State net operating loss carryforwards | 467,000 | 483,000 | 291,000 |
| Federal tax credit carryforwards | 152,000 | 152,000 | 152,000 |
| Investment losses not deducted | 709,000 | 709,000 | 1,532,000 |
| Total deferred income tax assets | 5,920,000 | 5,907,000 | 5,838,000 |
| Deferred income tax liabilities: | | | |
| Excess of tax over book depreciation and amortization | (625,000) | (616,000) | (620,000) |
| Prepaid expenses | (28,000) | (13,000) | (7,000) |
| Unrealized gain on investments | (1,557,000) | (2,237,000) | -- |
| Total deferred income tax liabilities | (2,210,000) | (2,866,000) | (627,000) |
| Valuation allowance | (3,710,000) | (3,041,000) | (5,211,000) |

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Net deferred income taxes recognized in the consolidated balance sheets \$ 0 \$ 0 \$ 0

At June 30, 2001, the Company had federal net operating loss carryforwards of approximately \$10,779,000 which expire in 2008 through 2021. At June 30, 2001, the Company had available for federal income tax purposes approximately \$41,000 of alternative minimum tax credit carryforwards which carry forward indefinitely and approximately \$111,000 of tax credit carryforwards which expire in the years 2007 through 2009. The Company also has approximately \$9,339,000 of state net operating loss carryforwards, which expire in 2003 through 2016, available to offset certain future state taxable income.

The income tax provision consists of the following:

| | 2001 | 2000 | 1999 |
|----------------------------|------|------|------|
| Current | | | |
| Federal. | \$ 0 | \$ 0 | \$ 0 |
| State. | 0 | 0 | 0 |
| Total income tax provision | \$ 0 | \$ 0 | \$ 0 |

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

| | 2001 | 2000 | 1999 |
|---|---------|---------|---------|
| Federal statutory income tax rate | (34.0)% | (34.0)% | (34.0)% |
| Losses for which no benefit was provided. . . | 17.5 | 35.3 | 29.3 |
| Non-deductible losses of subsidiaries | 15.6 | 27.6 | 3.2 |
| Other-net (principally stock options in 2000) | 0.9 | (28.9) | 1.5 |
| | ----- | ----- | ----- |
| Effective income tax rate | 0% | 0% | 0% |

5. LINE OF CREDIT FACILITY AND LONG-TERM DEBT

| | 2001 | 2000 |
|---|-------------|-------------|
| Long-term debt consists of the following: | | |
| Mortgage note, 7.5% due in monthly installments of \$27,793 with a final payment of \$3,048,253 due April 1, 2004, collateralized by real estate with a carrying value of approximately \$3,754,000 at June 30, 2001. | \$3,283,892 | \$3,364,324 |
| Less current maturities. | 86,766 | 80,432 |
| | ----- | ----- |
| Long-term debt | \$3,197,126 | \$3,283,892 |

Aggregate annual principal payments required under terms of the long-term debt agreement are as follows:

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| YEARS ENDING JUNE 30, | PRINCIPAL PAYMENTS |
|-----------------------|--------------------|
| 2002. | \$ 86,766 |
| 2003. | 93,600 |
| 2004. | 3,103,526 |
| 2005. | 0 |
| 2006. | 0 |
| | ----- |
| Total | \$ 3,283,892 |

At June 30, 2001, the Company had a \$4,000,000 demand line of credit facility with a commercial bank to meet its short-term borrowing needs. Borrowings against the line were payable on demand with interest payable monthly at the bank's reference rate, plus .25% (7.0% as of June 30, 2001). As of June 30, 2001, there were no borrowings against the line. Borrowings under the line of credit facility are collateralized by substantially all assets of the Company. The credit facility has covenants which require minimum levels of tangible net worth and income levels. The Company was not in compliance with the income level covenant at June 30, 2001. This non-compliance was waived by the lending institution.

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In March 1999, the Company refinanced its mortgage note on the Company's office and manufacturing facility. The Company incurred a prepayment penalty of approximately \$120,000, which was recorded as interest expense.

6. CONTINGENCIES

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

The Company received two grants from the State of Wisconsin for research and development of certain products. The grants were to be repaid only upon successful completion and marketing of the related product. Repayment of these grants was to be made on a sales by unit basis. Repayments approximated \$182,000 in 1999 and constituted full repayment of one of these grants. The repayments were charged to expense as the related products were sold. Since the second grant did not result in the successful completion and marketing of a product, the Company did not have to repay the grant.

7. STOCKHOLDERS' EQUITY

STOCK OPTIONS - In December 1992, the Board of Directors approved a new Employee Stock Option Plan and Non-Employee Stock Option Plan. No new stock options can be granted under the Employee Stock Option Plan and Non-Employee Stock Option Plan which existed prior to the approval of the new plans. The Board of Directors has authorized in connection with these new plans the issuance of 2,220,000 reserved shares of common stock of which 137,930 reserved shares of common stock remain available for future issuance under the stock option plans at June 30, 2001. The Board of Directors increased the number of reserved shares for issuance under the Plans from 1,720,000 to 2,220,000 during 2001. The activity during 1999, 2000 and 2001 for the above plans is summarized as follows:

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| | NUMBER OF SHARES | STOCK OPTIONS PRICE RANGE | WEIGHTED AVG. EXERCISE PRICE |
|---------------------------------------|---------------------|------------------------------|---------------------------------|
| Outstanding at July 1, 1998 | 839,700 | 1.88-3.63 | 2.50 |
| Granted | 993,700 | 1.50-1.88 | 1.74 |
| Cancelled | (636,800) | 1.69-3.00 | 2.06 |
| Exercised | (5,000) | 2.06 | 2.06 |
| ----- | | | |
| Outstanding at June 30, 1999. | 1,191,600 | 1.50-3.00 | 1.83 |
| Granted | 489,100 | 2.00-2.25 | 2.24 |
| Cancelled | (287,700) | 1.63-3.63 | 1.99 |
| Exercised | (240,100) | 1.50-2.75 | 1.91 |
| ----- | | | |
| Outstanding at June 30, 2000. | 1,152,900 | 1.50-2.75 | 1.96 |
| Granted | 780,520 | 1.88-3.69 | 2.47 |
| Cancelled | (279,100) | 1.88-2.75 | 2.01 |
| Exercised | (18,700) | 1.63-2.97 | 2.03 |
| ----- | | | |
| Outstanding at June 30, 2001. | 1,635,620 | 1.50-3.69 | 2.19 |
| Exercisable at June 30, 2001. | 735,120 | 1.50-3.69 | 2.11 |

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The following table summarizes information about stock options outstanding as of June 30, 2001:

| Range of Exercise Prices | OPTIONS OUTSTANDING | | | Weighted Average Exercise Price | OPTIONS E Shares Exercisable at June 30, 2001 |
|-----------------------------|---|--|----|---------------------------------------|--|
| | Shares Outstanding at June 30, 2001 | Weighted Average Remaining Contractual Life-Years | | | |
| 1.50-1.875 | 794,000 | 2.99 | \$ | 1.75 | 344,000 |
| 2.00-3.69. | 841,620 | 3.10 | | 2.61 | 391,120 |
| 1.50-3.69. | 1,635,620 | 3.05 | | 2.19 | 735,120 |

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

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," but applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for its plans. If the Company had elected to recognize compensation cost for the options granted during the years ended June 30, 2001, 2000 and 1999, consistent with the method prescribed by SFAS No. 123, net loss and net loss per share would have been changed to the pro forma amounts indicated below:

| | | |
|------|----------------------|------|
| | YEARS ENDED JUNE 30, | |
| 2001 | 2000 | 1999 |

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| | | | |
|---|--------------|--------------|----------------|
| Net income (loss)-as reported | \$ (178,232) | \$ (186,388) | \$ (4,388,171) |
| Net income (loss)-pro forma | \$ (507,678) | \$ (365,626) | \$ (4,555,200) |
| Net income (loss) per common share-as reported. | \$ (0.02) | \$ (0.02) | \$ (0.51) |
| Net income (loss) per common share-pro forma. . | \$ (0.05) | \$ (0.04) | \$ (0.53) |

Assumptions used:

| | | | |
|---|-------|-----|-----|
| Expected volatility | 37.5% | 23% | 15% |
| Risk-free interest rate | 5% | 6% | 5% |
| Expected option life (in years) | 4 | 4 | 3 |

| | | | |
|--|---------|---------|---------|
| Weighted average fair market value of options granted during the fiscal year ended June 30 | \$ 0.61 | \$ 0.38 | \$ 0.23 |
|--|---------|---------|---------|

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

STOCK WARRANTS - In September 1995, the Company executed a warrant agreement with a consultant. The warrant agreement provided for the issuance of warrants to purchase up to 150,000 shares of the common stock of the Company, exercisable at a price of \$2.00 per share. The warrant was exercisable as to 37,500 shares upon execution of the agreement and the warrants to purchase the remaining 112,500 shares were to become exercisable if certain performance parameters were achieved by September 1996. Such parameters were not met as of such date. In January 1997, the agreement was extended and the parameters were changed. By June 30, 1997, warrants to purchase the remaining 112,500 shares of

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common stock at a price of \$2.00 per share became exercisable. The warrant holder exercised rights and purchased 41,000 shares of common stock at \$2.00 per share during the year ended June 30, 1998. The warrants were exercised to purchase 15,000 shares of common stock at \$2.00 per share during the year ended June 30, 2001, and the remainder of such warrants expired.

In February 1998, the Company executed a similar warrant agreement with the consultant. The warrant agreement provides for the issuance of warrants to purchase up to 150,000 shares of common stock at a price of \$3.00 per share. The warrant is exercisable as to 30,000 shares upon execution of the agreement and the warrants to purchase the remaining 120,000 shares will be exercisable if certain performance parameters are achieved by February 1999. No such parameters were achieved. During the year ended June 30, 1998, the Company recognized \$23,065 of expense related to the value of the services performed under the agreement. As of June 30, 2001, 30,000 warrants were exercisable. Such warrants expire in February 2003.

In December 2000, the Company executed another warrant agreement with the consultant. The warrant agreement provides for the issuance of warrants to purchase up to 70,000 shares of common stock at a price of \$1.875 per share. The warrant vests over a four year period in four equal increments each year on the anniversary date of the warrant. The warrant terminates as to any shares that are unvested at the time the consultant ceases to provide consulting services to the Company. As of June 30, 2001, none of these warrants were exercisable. Such warrants expire in December 2005.

COMMITMENT TO ISSUE SHARES OF COMMON STOCK - In April 1998, the Company agreed to and accepted the patent rights assigned to them by a third party with respect to certain technology related to the transmission of clinical data. In consideration for the patent, the Company has agreed to provide the third party

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with 400,000 shares of common stock payable over a four-year time period with additional consideration of up to 112,000 shares contingent upon the achievement of certain sales levels. The Company recorded a charge to operations of \$900,000 in fiscal 1998 with respect to the value of the in-process technology which was expensed as research and development costs. The 400,000 shares to be issued have been considered to be outstanding shares for purposes of computing basic and diluted income (loss) per common share in 1998. During 1999, the Company renegotiated the agreement and issued the third party 350,000 shares instead of the 400,000 shares payable over four years and the 112,000 contingent shares.

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

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

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8. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan which covers substantially all employees. Company contributions to the plan are discretionary and determined annually by the Company's Board of Directors. The Company's contributions were approximately \$87,000, \$77,000, and \$84,000 in 2001, 2000 and 1999, respectively.

9. BUSINESS AND CREDIT CONCENTRATIONS

The Company is a manufacturer of medical monitors and telemetry products whose customers include hospitals and alternative health care sites throughout the world. Although the Company's products are sold primarily to health care providers, concentrations of credit risk with respect to trade accounts receivable are limited due to the Company's large number of customers and their geographic dispersion. The Company currently coordinates substantially all international sales and distribution activities through its headquarters in Waukesha, Wisconsin. Such activities were previously provided by the Company with the assistance of Criticare International. Identifiable assets located outside of the United States are insignificant in relation to the Company's total assets. Net export sales by geographic area are as follows:

| | 2001 | 2000 | 1999 |
|--------------------------------------|--------------|--------------|--------------|
| Europe and Middle East | \$ 6,833,000 | \$ 5,437,000 | \$ 4,635,000 |
| Pacific Rim. | 2,313,000 | 2,662,000 | 2,243,000 |
| Canada and Central and South America | 2,217,000 | 3,035,000 | 3,634,000 |

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| | | | |
|----------------------------|--------------|--------------|--------------|
| Export net sales | \$11,363,000 | \$11,134,000 | \$10,512,000 |
| U.S. net sales | 16,373,000 | 16,020,000 | 18,001,000 |
| Total net sales. | 27,736,000 | 27,154,000 | 28,513,000 |

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

10. OTHER BUSINESS CONCENTRATIONS

During 1999, the Company entered into an OEM agreement with a customer. Sales to this customer approximated \$3,383,000, \$2,031,000, and \$4,360,000 in fiscal 2001, 2000, and 1999, respectively. These sales represented approximately 12%, 8%, and 15% of the Company's total sales, respectively. This customer had a receivable balance of \$630,716, \$935,520, and \$448,546 on June 30, 2001, 2000, and 1999, respectively, which represented 9%, 14%, and 7% of the Company's total receivables as of these dates.

The Company also has a supplier that it made purchases from totaling approximately \$4,461,000, \$3,358,000, and \$3,087,000 in fiscal 2001, 2000, and 1999, respectively. These purchases represent approximately 19%, 16%, and 16% of the Company's total purchases, respectively. The Company had a payable balance owed to this vendor of \$144,131, \$220,999, and \$122,603 on June 30, 2001, 2000, and 1999, respectively, which represents 4%, 8%, and 4% of the Company's total payables as of these dates.

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11. COMMITMENTS

The Company leases certain operating equipment under various operating leases for varying periods through fiscal 2006. Rent expense was \$165,361 in 2001 and \$207,553 in 2000.

The future minimum rental commitments under these leases are as follows:

| | Year ended June 30, |
|------------|---------------------|
| 2002 | \$91,222 |
| 2003 | 35,084 |
| 2004 | 22,008 |
| 2005 | 18,831 |
| Thereafter | 15,693 |
| | ----- |
| Total | \$182,838 |

During fiscal 2001 the Company entered into supply partnership agreements with two offshore contract manufacturing firms that exclusively manufacture medical devices in a regulated environment. These two firms will manufacture specific products designated by the Company in accordance with formal purchase orders. The initial term of the agreements is for a period of three years and is automatically extended for additional periods of two years each, unless either party gives written notice at least sixty days prior to the end of the initial term or the then current extension term. To ensure an adequate supply of products manufactured by these companies is maintained, the agreements require

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that these firms keep on hand in their finished goods inventories one full month of supply of all products under current purchase orders, in addition to a one month supply that will be maintained by the Company. At June 30, 2001, a one month supply of product maintained at these two firms would total approximately \$475,000. In the event the Company would cancel a purchase order under either of these agreements, the Company would be required to purchase at cost all raw materials, work-in-progress and finished goods inventories for that purchase order. In addition, any property or equipment that these firms purchased specifically for the production of the Company's products would be purchased at mutually agreed upon prices. There have not been any purchase order cancellations under these agreements.

12. SEVERANCE PAY

During November 1998, the two co-founders of the Company resigned from their positions. The Company has provided each of these individuals with a severance agreement, which includes a portion of their salary and fringe benefits for a period which approximates three years. The salary portion of the severance expires on November 30, 2001 and the fringe benefit portion expires on September 30, 2001, with the exception of health and dental benefits, which continue until age 65 or comparable coverage is available through another employer.

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INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheets of Criticare Systems, Inc. and subsidiaries as of June 30, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended June 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Criticare Systems, Inc. and subsidiaries at June 30, 2001 and 2000 and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2001, in conformity with generally accepted accounting principles.

/s/ BDO Seidman, LLP
Milwaukee, Wisconsin
August 21, 2001

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QUARTERLY RESULTS

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The following table contains quarterly information, which includes all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for a fair presentation. The Company recorded a gain of \$2,500,000 in the quarter ended September 30, 1999 related to the sale of Immtech stock. This item was an unusual, nonrecurring adjustment.

| | QUARTERS ENDED | | | | | | |
|--|---------------------------------------|-------------------|------------------|-------------------|------------------|-------------------|----|
| | JUNE 30, 2001 | MARCH 31, 2001 | DEC. 31, 2000 | SEPT. 30, 2000 | JUNE 30, 2000 | MARCH 31, 2000 | D |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | | | | | |
| Net sales | \$ 7,678 | \$ 7,264 | \$ 6,564 | \$ 6,230 | \$ 7,519 | \$ 6,131 | \$ |
| Gross profit | 3,252 | 2,923 | 2,581 | 2,511 | 2,326 | 2,235 | |
| (Loss) income from operations | (149) | 37 | 134 | (108) | (1,317) | (1,143) | |
| Net (loss) income | (161) | 44 | 106 | (166) | (1,367) | (1,197) | |
| Net (loss) income per common share-Basic | (0.01) | 0.00 | 0.01 | (0.02) | (0.16) | (0.14) | |
| -Diluted | (0.01) | 0.00 | 0.01 | (0.02) | (0.16) | (0.14) | |

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

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

FINANCIAL DISCLOSURE.

The Company's change in accountants for the 1999 fiscal year was previously reported in the Company's Current Report on Form 8-K filed on October 13, 1999, as amended on October 25, 1999, and the Company's Current Report on Form 8-K filed on November 5, 1999.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information regarding the executive officers and directors of the Company is incorporated herein by reference to the discussions under "Nominees for Election as Director," "Other Directors," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Executive Officers" in the Company's Proxy Statement for the 2001 Annual Meeting of Stockholders (the "Criticare Proxy Statement") which will be filed on or before October 29, 2001.

Item 11. EXECUTIVE COMPENSATION.

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

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

Incorporated herein by reference to the discussion under "Security Ownership" in the Criticare Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Incorporated herein by reference to the discussion under "Employment Agreements and Severance Arrangements" in the Criticare Proxy Statement.

PART IV

Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

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

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

Consolidated Balance Sheets - as of June 30, 2001 and 2000.

Consolidated Statements of Operations - for the years ended June 30, 2001, 2000 and 1999.

Consolidated Statements of Stockholders' Equity - for the years ended June 30, 2001, 2000 and 1999.

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Consolidated Statements of Cash Flows - for the years ended June 30, 2001, 2000 and 1999.

Notes to consolidated financial statements.

2. Financial Statement Schedules:

Independent Auditors' Report.

Financial Statement Schedule for the years ending June 30, 2001, 2000 and 1999:

| Schedule Number | Description | Page |
|-----------------|--|------|
| II | Valuation and Qualifying Accounts and Reserves | 40 |

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

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have been omitted.

3. Exhibits:

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

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

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

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

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10.1* 1999 Employee Stock Purchase Plan (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

10.2* 1992 Employee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-60644).

10.3* 1992 Nonemployee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-60214).

10.4* 1987 Employee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-33497).

10.5* 1987 Nonemployee Stock Option Plan (incorporated by reference to the Company's Registration Statement on Form S-8, Registration No. 33-40038).

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

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10.7* Severance Agreement, dated as of November 16, 1998, of Gerhard J. Von der Ruhr (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).

10.8* Severance Agreement, dated as of November 16, 1998, of N.C. Joseph Lai (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).

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

10.10* Employment Agreement of Stephen D. Okland, (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

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

10.12 Supply Partnership Agreement, dated as of August 1, 2000, between the Company and BioCare Corporation.

10.13 Supply Agreement, dated as of October 26, 2000, between the Company and TriVirix International Limited.

21 Subsidiaries (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended June 30, 1999).

23.1 Consent of BDO Seidman, LLP

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

* Management contract or compensatory plan or arrangement.

(b) Reports on Form 8-K.

The Company filed no reports on Form 8-K during the quarter ended June 30, 2001.

(c) Exhibits.

The response to this portion of Item 14 is submitted as a separate section of this report.

(d) Financial Statement Schedules.

The response to this portion of Item 14 is submitted as a separate section of this report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CRITICARE SYSTEMS, INC.

By /s/ Emil H. Soika

Emil H. Soika, President
and Chief Executive Officer

Date: September 26, 2001

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Emil H. Soika and Michael J. Sallmann, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form

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10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

| Signature | Title | Date |
|---|---|--------------------|
| /s/ Emil H. Soika ----- Emil H. Soika | President, Chief Executive Officer and Director (Principal Executive Officer) | September 26, 2001 |
| /s/ Michael J. Sallmann ----- Michael J. Sallmann | Vice President-Finance and Secretary (Principal Financial and Accounting Officer) | September 26, 2001 |
| /s/ Karsten Houm ----- Karsten Houm | Chairman of the Board and Director | September 26, 2001 |
| /s/ Milton Datsopoulos ----- Milton Datsopoulos | Director | September 26, 2001 |
| /s/ N.C. Joseph Lai ----- N.C. Joseph Lai, Ph.D. | Director | September 26, 2001 |
| /s/ Higgins Bailey ----- Dr. Higgins Bailey | Director | September 26, 2001 |
| /s/ Jeffrey T. Barnes ----- Jeffrey T. Barnes | Director | September 26, 2001 |
| /s/ Stephen K. Tannenbaum ----- Stephen K. Tannenbaum | Director | September 26, 2001 |

INDEPENDENT AUDITORS' REPORT

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

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The audits referred to in our report dated August 21, 2001 relating to the consolidated financial statements of Criticare Systems, Inc., which is contained in Item 8 of this Form 10-K included the audit of the financial statement schedules listed in Item 14. These financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statement schedules based upon our audits.

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

/s/ BDO Seidman, LLP
Milwaukee, Wisconsin
August 21, 2001

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SCHEDULE II

CRITICARE SYSTEMS, INC.

VALUATION AND QUALIFYING ACCOUNTS AND RESERVES
FOR THE YEARS ENDED JUNE 30, 2001, 2000 AND 1999

| Description | Column A ----- | Column B ----- | Column C ----- | Column D ----- | Column E ----- |
|--|-------------------|--------------------------------------|-------------------------------------|-------------------|--------------------------------|
| ----- | | Balance at Beginning of Period | Charged to Costs and Expenses | Deductions | Balance at End of Period |
| ----- | | ----- | ----- | ----- | ----- |
| YEAR ENDED JUNE 30, 1999: | | | | | |
| Allowance for doubtful accounts | \$ | 300,000 | \$ 380,004 | \$ 305,004 | \$ 375,000 |
| Reserve for sales returns and allowances | \$ | 100,000 | \$ 760,194 | \$ 800,194 | \$ 60,000 |
| Reserve for obsolete inventory | \$ | 37,920 | \$ 521,684 | \$ -- | \$ 559,604 |
| YEAR ENDED JUNE 30, 2000: | | | | | |
| Allowance for doubtful accounts | \$ | 375,000 | \$ 1,160,614 | \$ 235,614 | \$ 1,300,000 |
| Reserve for sales returns and allowances | \$ | 60,000 | \$ 554,101 | \$ 554,101 | \$ 60,000 |
| Reserve for obsolete inventory | \$ | 559,604 | \$ 94,310 | \$ 253,914 | \$ 400,000 |
| YEAR ENDED JUNE 30, 2001: | | | | | |
| Allowance for doubtful accounts | \$ | 1,300,000 | \$ 685,873 | \$ 985,873 | \$ 1,000,000 |
| Reserve for sales returns and allowances | \$ | 60,000 | \$ -- | \$ -- | \$ 60,000 |
| Reserve for obsolete inventory | \$ | 400,000 | \$ -- | \$ 75,000 | \$ 325,000 |

