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CRITICARE SYSTEMS INC /DE/
Form S-3
May 21, 2002

Reg.No. 333-_____

As filed with the Securities and Exchange Commission on May 20, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
Under the Securities Act of 1933

CRITICARE SYSTEMS, INC.
(Exact Name of Registrant as Specified in Its Charter)

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

| | |
|--|--|
| 20925 Crossroads Circle, Waukesha, WI 53186 | (262) 798-8282 |
| ----- | ----- |
| (Address, including Zip Code of Registrant's Principal Executive Offices) | (Telephone Number, Including Area Code) |

Emil H. Soika
President and Chief Executive Officer
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
(262) 798-8282

(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

Copies of all communications to:
Reinhart Boerner Van Deuren s.c.
1000 North Water Street, Suite 2100
Milwaukee, WI 53202
Attn: Benjamin G. Lombard, Esq.
Telephone: (414) 298-1000
Facsimile: (414) 298-8097

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or reinvestment plans, please check the following box. []

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. []

CALCULATION OF REGISTRATION FEE

| Title of Shares to be Registered | Amount to be Registered | Proposed Maximum Offering Price Per Share (1) | Proposed Maximum Aggregate Offering Price (1) | Amount of Registration Fee |
|----------------------------------|-------------------------|---|---|----------------------------|
| Common Stock, \$.04 Par Value | 100,000 | \$5.28 | \$528,000 | \$49 |

(1) CALCULATED IN ACCORDANCE WITH RULE 457(C) BASED ON THE AVERAGE OF THE HIGH AND LOW SALES PRICES OF THE COMMON STOCK AS REPORTED ON THE NASDAQ NATIONAL MARKET ON MAY 17, 2002, SOLELY FOR PURPOSES OF CALCULATING THE AMOUNT OF THE REGISTRATION FEE.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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PRELIMINARY PROSPECTUS DATED MAY 20, 2002

100,000 SHARES

CRITICARE SYSTEMS, INC.

COMMON STOCK

C.C.R.I. Corporation is offering for sale up to 100,000 shares of our common stock which are issuable by us upon exercise of warrants held by the selling stockholder. Because the shares offered under this prospectus will be sold by C.C.R.I. Corporation, we will not receive any proceeds from the sale of these shares.

Shares of our common stock are traded on the Nasdaq National Market.

Trading Symbol on Nasdaq National Market: CXIM
Last Sale Price on May 17, 2002: \$5.296 per share

CONSIDER CAREFULLY THE "RISK FACTORS" BEGINNING ON PAGE 4 OF THIS PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES, OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

_____, 2002.

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YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROSPECTUS OR THE OTHER INFORMATION WE HAVE REFERRED YOU TO. WE HAVE NOT AUTHORIZED ANYONE TO PROVIDE YOU WITH INFORMATION THAT IS DIFFERENT. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY ANY SECURITY OTHER THAN THE SHARES OF COMMON STOCK OFFERED BY THIS PROSPECTUS, NOR DOES IT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY SHARES OF COMMON STOCK IN ANY JURISDICTION WHERE SUCH OFFER OR SOLICITATION WOULD BE UNLAWFUL. YOU SHOULD ASSUME THAT THE INFORMATION IN THIS PROSPECTUS IS ACCURATE ONLY AS OF THE DATE OF THIS PROSPECTUS, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR OF ANY SALE OF COMMON STOCK.

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SUMMARY

This summary highlights selected information from this document and from the documents that we incorporate by reference. For a more complete description of the offering and Criticare, you should read carefully this entire document and the documents to which we have referred you. See "Where You Can Find More Information" (page 9).

CRITICARE SYSTEMS, INC.
20925 Crossroads Circle
Waukesha, Wisconsin 53186
(262) 798-8282

We design, manufacture and market vital signs and gas monitoring instruments and related noninvasive sensors used to monitor patients in many healthcare settings. 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. Our monitoring equipment improves patient safety by delivering accurate, comprehensive and instantaneous patient information to physicians and other health service clinicians. Our 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 settings, we have developed a broad line of patient monitors which combine one or more of our patented or other proprietary technologies, for monitoring:

- oxygen saturation;
- carbon dioxide; and
- anesthetic agents,

with standard monitoring technologies that provide:

- electrocardiogram;
- invasive and noninvasive blood pressure;
- temperature;
- heart rate; and
- respiration rate.

In addition, our 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

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extensive and costly personnel and equipment resources.

THE OFFERING

| | |
|---|---|
| Common stock offered by the selling shareholder | 100,000 shares |
| Common stock outstanding as of April 30, 2002 | 11,059,624 shares |
| Proceeds from sale | We will not receive any proceeds from the sale of these shares. |

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RISK FACTORS

Before purchasing our stock, you should carefully consider the following risk factors and the other information contained in this prospectus.

WE FACE SIGNIFICANT COMPETITION IN OUR MARKETS. AS A RESULT, WE MAY NOT BE ABLE TO INCREASE OUR MARKET SHARE OR PROFIT MARGINS.

The markets for our products are highly competitive. Many of our competitors have greater:

- engineering resources;
- research and development resources;
- manufacturing resources;
- financial and marketing resources; and
- market presence and reputation.

We have historically experienced substantial price competition for our products and price competition is likely to continue.

OUR GROWING RELIANCE ON OFFSHORE CONTRACT MANUFACTURING MAKES OUR BUSINESS SUSCEPTIBLE TO NUMEROUS RISKS THAT COULD AFFECT OUR PROFITABILITY.

In response to pricing pressure, in fiscal 2001 we entered into agreements with two offshore contract manufacturing firms located in Ireland and Taiwan, respectively. We completed the transition of the production of substantially all of our established product lines to these manufacturing firms at the end of calendar 2001. Our reliance on offshore contract manufacturing will subject us to numerous risks, including the following:

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

WE HAVE A HISTORY OF LOSSES. IF WE DO NOT ACHIEVE PROFITABILITY, OUR FINANCIAL CONDITION AND STOCK PRICE COULD SUFFER.

We had net losses of \$186,388 in fiscal 2000, \$178,232 in fiscal 2001 and \$1,111,106 in the first nine months of fiscal 2002. We cannot assure you that we will be able to achieve or sustain profitability in future periods.

OUR SUCCESS DEPENDS ON OUR ABILITY TO INTRODUCE NEW PRODUCTS.

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Our future growth will depend in large part upon our ability to continue to conceive, design, and market new products and upon continuing market acceptance of our existing and future products. Any significant delays in the introduction of, or the failure to introduce, new products or additions to our existing product lines or the failure of our existing or future products to maintain or receive market acceptance could have a material adverse effect on our business, results of operations or financial condition.

OUR SUCCESS DEPENDS ON OUR ABILITY TO PROTECT OUR INTELLECTUAL PROPERTY.

We rely on our patented and other proprietary technology including:

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

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

- our proprietary information will not become known to competitors;
- others will not independently develop substantially equivalent or better products that do not infringe on our intellectual property rights; or
- others will not challenge or assert rights in, and ownership of, our patents and other proprietary rights.

Although none of our United States patents expire before 2004, to the extent competitors develop equivalent or superior non-infringing technology in these areas, or to the extent that we are unable to enforce our patents, our ability to market and sell our products could be harmed.

INTERNATIONAL SALES MAKE OUR BUSINESS SUSCEPTIBLE TO NUMEROUS INTERNATIONAL BUSINESS RISKS AND CHALLENGES THAT COULD AFFECT OUR PROFITABILITY.

International sales accounted for 41% of our total net sales for the 2001 fiscal year. We expect that international sales will continue to constitute a significant portion of our business. Although we sell our products in United States dollars and are not subject to significant currency risks, an increase in the value of the United States dollar relative to foreign currencies in our international markets could make our products less price competitive in such markets. Also, our international sales are subject to the risks inherent in doing business abroad, including:

- delays in shipments;
- increases in import duties and tariffs; and
- changes in foreign regulations and political climate.

WE OPERATE IN A HIGHLY REGULATED INDUSTRY.

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

- substantially delay or prevent the introduction of new products;
- materially increase the costs of any new product introductions;
- interfere with or require cessation of product manufacturing and

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- marketing; and
- result in product recalls.

Additionally, adoption of new regulations or modifications to applicable regulations could harm our business.

HEALTH CARE COST CONTAINMENT PROGRAMS COULD ADVERSELY AFFECT OUR DOMESTIC SALES.

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

OUR BUSINESS IS SUBJECT TO POSSIBLE PRODUCT LIABILITY EXPOSURE.

As a manufacturer of medical diagnostic equipment, we could face product liability claims. We have had no product liability claims to date and maintain product liability insurance. However, we can make no assurance that our insurance coverage will be adequate to cover any product liability claims which arise in the future or that it will continue to be available at reasonable prices.

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OUR STOCK PRICE MAY FLUCTUATE, INCREASING THE RISK TO INVESTORS IN OUR COMMON STOCK.

Market prices of securities of medical technology companies, including our common stock, have experienced significant volatility from time to time. There may be volatility in the market price of our common stock due to factors that may or may not relate to our performance. Various factors and events may have a significant impact on the market price of our common stock such as:

- announcements by us or our competitors concerning new product developments;
- governmental approvals, regulations or actions;
- developments or disputes relating to patent or proprietary rights;
- public concern over product liability; and
- general economic and market conditions.

In addition, our quarterly results have historically fluctuated.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this document that are subject to risks and uncertainties. Without limitation, these forward-looking statements include statements:

- regarding new products we may introduce in the future;
- about our business strategy and plans;
- about the adequacy of our working capital and other financial resources; and
- that are not of an historical nature.

When we use words such as "believes," "expects," "anticipates," "will," "would," "projects" or similar expressions, we are making forward-looking statements. You should note that forward-looking statements rely on a number of

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assumptions concerning future events, and are subject to a number of uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the statements made. These factors include those discussed under the caption "Risk Factors" in this prospectus. Please note that we disclaim any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares by the selling stockholder. If the selling stockholder exercises its warrants in full we would receive proceeds of \$221,250 from the selling stockholder. We intend to use any proceeds from the exercise of the warrants by the selling stockholder for general business purposes, including working capital.

SELLING STOCKHOLDER

All of the shares of our common stock offered for sale pursuant to this prospectus are being offered by C.C.R.I. Corporation. Beginning on September 21, 1995, we engaged the selling stockholder as a consultant to provide investor relations and development services. In February 1998, we issued a warrant to purchase up to 150,000 shares of our common stock to the selling stockholder with an exercise price of \$3.00 per share. This warrant was exercisable as to 30,000 shares on issuance and the remaining 120,000 shares underlying this warrant were to become exercisable if certain performance parameters were achieved by February 1999. Since these performance parameters were not achieved this warrant is currently exercisable for 30,000 shares. This warrant expires in February 2003. In December 2000, we issued a warrant to purchase up to 70,000 shares of our common stock to the selling stockholder with an exercise price of \$1.875 per share. This 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 us. This warrant expires in December 2005.

| | Shares of Common Stock Owned Prior to Offering ----- | Shares Offered for Sale Hereby ----- | Shares to be Owned After the Offering* | |
|----------------------|--|--|---|------------------|
| | | | Number ----- | Percent ----- |
| C.C.R.I. Corporation | 100,000 | 100,000 | - | - |