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ICU MEDICAL INC/DE
Form 8-K
March 02, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported) February 25, 2005

ICU MEDICAL, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction
of incorporation)

33-0022692

(I.R.S. Employer Identification No.)

0-19974

(Commission File Number)

951 Calle Amanecer, San Clemente, California

(Address of principal executive offices)

92673

(Zip Code)

(949) 366-2183

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

INFORMATION TO BE INCLUDED IN THE REPORT

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On February 25, 2005, the Company and Hospira, Inc. ("Hospira") entered into a twenty-year Manufacturing, Commercialization and Development Agreement

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("MCDA"), an Asset Purchase Agreement and a Real Estate Purchase Agreement. Under the Asset Purchase Agreement and a Real Estate Purchase Agreement, the Company will acquire Hospira's Salt Lake City, Utah manufacturing facility, related capital equipment and certain inventories for approximately \$35 million in cash. Hospira currently manufactures most of its critical care products for sale and distribution in the United States at the Salt Lake City facility. The purchase price is subject to adjustment based on the net book value of certain of the assets at closing. The acquisition is expected to close early in the second quarter of 2005, subject to customary closing conditions.

Under the MCDA, which will become effective on the closing of the acquisition under the Asset Purchase Agreement and a Real Estate Purchase Agreement, the Company will produce for sale to Hospira on an exclusive basis substantially all the products currently manufactured by Hospira at the Salt Lake City plant. Hospira will retain commercial responsibility for the products the Company will be producing, including sales, marketing, distribution, customer contracts, customer service and billing. The majority of the products the Company will be producing under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. The Company has also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira, and has also committed to provide certain sales specialist support. The Company's prices and its gross margins on the products it sells to Hospira under the MCDA will be based on cost savings that the Company is able to achieve in producing those products over Hospira's current cost to manufacture those same products. The Company expects to move the production to its current facilities or other lower-cost locations over the next several years. The Company estimates that sales under this agreement will exceed \$50 million in 2005, with only small profits, with increasing sales and profits in future years.

Special Considerations

THESE AGREEMENTS INCREASE THE COMPANY'S DEPENDENCE ON HOSPIRA FOR A SUBSTANTIAL PORTION OF ITS SALES. ANY CHANGE IN THE ARRANGEMENTS WITH HOSPIRA OR DECLINE IN THE COMPANY'S SALES TO IT COULD RESULT IN A SIGNIFICANT REDUCTION IN THE COMPANY'S SALES AND PROFITS.

The Company has substantially increased its sales to Hospira over the years. In 2003, Hospira accounted for 69% of the Company's sales; this decreased to 55% in 2004 because Hospira reduced purchases from the Company to reduce its inventories of the Company's products, and absent the MCDA, the percentage of the Company's sales accounted for by Hospira would be expected to increase in 2005. The percentage of the Company's sales attributable to Hospira will increase even further once it begins manufacturing under the MCDA.

In 2004, Hospira substantially reduced its purchases of certain of the Company's products because it was reducing its inventories of the Company's products. This caused a significant reduction in the Company's sales and led to a net loss in the Company's third and fourth quarters of 2004. There is no assurance that Hospira will not attempt to reduce its inventory of products manufactured under the MCDA; action of that type could have an adverse effect on the Company's operations and its profits under the MCDA.

Under the MCDA, The Company will provide certain sales support to Hospira. However, The Company's ability to maintain or increase level of sales of these products will depend on Hospira's commitment to and the success of its sales and marketing efforts.

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Under the terms of the Company's agreements with Hospira, including the MCDA, the Company is dependent on the marketing and sales efforts of Hospira for a large percentage of its sales and Hospira determines the prices at which the products that the Company sells to Hospira will be sold to its customers. Hospira's rights to sell products the Company will produce under the MCDA are exclusive. If Hospira is unable to maintain its position in the marketplace, or if Hospira should experience significant price deterioration, the Company's sales and operations could be adversely affected.

IF HOSPIRA IS UNABLE TO REVERSE THE DECLINE IN SALES OF PRODUCTS PRODUCED CURRENTLY PRODUCED AT THE SALT LAKE CITY FACILITY, THE COMPANY'S FINANCIAL PERFORMANCE MAY BE ADVERSELY AFFECTED.

Hospira has experienced in recent years a decline in sales of products manufactured at the Salt Lake City facility. Hospira has informed the Company that they have recently commenced efforts to increase sales of those products. However, there is no assurance that those efforts will be successful. A continued decline in sales would reduce Hospira's requirements for product that we plan to produce under the MCDA, and if that occurs, the Company's sales and operations would be adversely affected.

IF THE COMPANY IS UNABLE TO MANAGE EFFECTIVELY ITS OPERATIONS UNDER THE MCDA, ITS FINANCIAL PERFORMANCE MAY BE ADVERSELY AFFECTED.

The performance of the MCDA under which the Company will produce critical care products for Hospira, the acquisition of related manufacturing assets, the addition of more than 750 production personnel, the relocation of manufacturing operations, the implementation of new manufacturing and assembly processes and techniques and the establishment of financial controls will impose a significant burden on the Company's management, human resources, operating and financial and accounting functions. The Company will need to expand its capabilities in each of these areas and devote significant time and effort to integrating the production under the MCDA with its existing operations, all of which will divert management's attention from the Company's current operations. In addition the Company may require additional expertise, capability and capacity that can best be obtained through other acquisitions.

The Sarbanes-Oxley Act of 2002 imposed significant new requirements on public companies. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requiring that our independent registered public accounting firm audit and report on the design and efficacy of internal controls has been extremely expensive for the Company. Although the Company expects to reduce the expense in 2005, it is uncertain that it will be able to do so because we do not know the scope of work required at the Salt Lake City facility and the impact, if any, on the scope of work at its other facilities. Further, there is no certainty that the Company will receive unqualified reports on its internal controls from its independent registered public accounting firm and what actions might be taken by securities regulators if the Company is unable to obtain an unqualified report.

IF THE COMPANY IS UNABLE TO REDUCE SUBSTANTIALLY THE COST OF MANUFACTURING PRODUCTS THAT IT WILL SELL TO HOSPIRA UNDER THE MCDA, IT MAY NOT BE ABLE TO PRODUCE AND SELL SUCH PRODUCTS PROFITABLY, AND ITS PROFIT MARGINS MAY DECLINE.

The prices at which the Company will sell products to Hospira and the gross margins that it will realize under the MCDA will depend on the cost savings that it is able to achieve in producing those products over Hospira's cost to manufacture the same products. Achieving substantial cost reductions will require moving manufacturing operations to lower-cost locations and the development and implementation of innovative manufacturing and assembly

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processes and techniques. There is no assurance that these efforts will be successful. If the Company is unable to achieve the cost savings that it expects, it may not be able to sell products manufactured under the MCDA profitably, and its profit margins may decline.

Forward Looking Statements

This report describes certain of the Company's expectations and beliefs about its future. These statements about the future are "forward looking statements." They are based on the best information currently available to the Company and assumptions that the Company believes are reasonable, but the Company does not intend the statements to be representations as to future results. Future results are subject to risks and uncertainties, including those described above in this report and the Risk Factors in our Current Report on Form 8-K to the Securities and Exchange Commission dated February 15, 2002, which is incorporated herein by reference, and actual results in the future may differ materially from the Company's current expectations. We disclaim any obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

- (c) Exhibits
- 99.1 Press release, dated February 28, 2005 announcing Hospira, Inc. and ICU Medical, Inc. sign a Manufacturing, Commercialization and Development Agreement for Critical Care Products.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 2, 2005

ICU MEDICAL, INC.

/s/ Francis J. O'Brien

Francis J. O'Brien
Secretary, Treasurer and
Chief Financial Officer