

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): November 5, 1998

ICU MEDICAL, INC.  
(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	0-19974 (Commission File Number)	33-0022692 (I.R.S. Employer Identification No.)
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951 Calle Amanecer  
San Clemente, California 92673  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (714) 366-2183

ITEM 5. OTHER EVENTS.

ICU Medical, Inc. (the "Company") from time to time makes forward looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, in reports and registration statements filed by the Company with the Securities and Exchange Commission and in communications by the Company with its stockholders and the investing public. Such forward looking statements involve a number of risks and uncertainties. The Company has briefly summarized its business below and described certain risks associated with its business. Investors should carefully read and consider the risk factors when evaluating the forward looking statements in the Company's reports and registration statements and in its public communications.

THE COMPANY

The Company develops, manufactures and sells proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. The Company's subsidiary, Budget Medical Products ("BMP"), develops, manufactures and sells low-cost, generic and custom I.V. sets.

The Company's I.V. connectors are designed to prevent accidental disconnections of I.V. lines, and to protect healthcare workers and their patients from the spread of infectious diseases, such as Hepatitis B and Human Immunodeficiency Virus ("HIV"), by significantly reducing the risk of accidental needlesticks. The CLAVE(R), a one-piece, needleless I.V. connection device, accounts for almost 70% of the Company's sales. The Company believes that the CLAVE offers healthcare providers an advantageous combination of safety, ease of use, reliability and cost effectiveness.

The Company has strategic supply and distribution agreements with two of the largest worldwide suppliers of I.V. products, B.Braun Medical, Inc. ("B.Braun/McGaw") and Abbott Laboratories ("Abbott"). The agreements (as currently amended, referred to as the "B.Braun/McGaw Agreement" and the "Abbott Agreement") provide that B.Braun/McGaw and Abbott may sell the Company's

products as components in certain prepackaged I.V. sets distributed by B.Braun/McGaw and Abbott. Under these agreements, B.Braun/McGaw and Abbott may offer these integrated products to large hospitals, hospital chains and home healthcare providers, including those with which they have established full-line supply contracts for I.V. products. The B.Braun/McGaw extends to December 2002, and the Abbott Agreement extends to April 2002. The Company also distributes its products through a network of independent distributors.

Heightened awareness of the risk of infection from needlesticks and the substantial expense to healthcare providers of complying with regulatory protocols when

2

needlesticks occur, have led to growing demand for safe medical devices such as the Company's protective I.V. connectors. In addition, Occupational Safety and Health Administration ("OSHA") regulations require healthcare providers to implement "universal precautions" to minimize their employees exposure to blood and body fluids.

The Company's I.V. connector products offer various combinations of features including needleless or enclosed needle connection systems and positive locking mechanisms. The Lopez Valve, designed to be connected into nasogastric tube systems, creates a closed system to prevent contact with body fluids in enteral feeding procedures. The Company has recently launched two new products. The CLC 2000 is a one piece, swabbable connector engineered to prevent the backflow of blood into a catheter. The 1o2 Valve, a drug delivery system incorporating a one-way check valve and a button for the infusion and aspiration of I.V. fluids. The Company has several new products under development, including new versions of the CLAVE. The Company has patents or pending patent applications on each of its current connector products and the 1o2 Valve.

In late 1995, the Company organized BMP as a wholly-owned subsidiary to service the low end of the safe medical connector market. BMP manufactures, markets and distributes low-cost I.V. sets and custom I.V. sets incorporating the CLAVE.

Hospitals and other healthcare providers purchase I.V. sets that are both standard manufacturers' catalog items and custom sets where the hospital, or possibly the individual doctor, specifies the desired features such as tubing size and length and the number, spacing and type of ports and connectors.

The Company believes that BMP will be able to offer customers substantially shorter delivery times and lower costs than other manufacturers of custom I.V. sets can currently offer. To reduce the costs of the labor intensive assembly of I.V. sets, the Company is constructing an assembly facility in Ensenada, Baja California, Mexico. To reduce the delivery times, BMP expects to use the Company's proprietary software currently under development for customer orders and order tracking, combined with an innovative system currently under development to coordinate manufacture of components in the U.S., assembly of components into sets in Mexico and distribution of finished products.

Because the above description of the Company is a summary, it does not contain all the information about the Company's business and products that may be important to investors. Investors should read the more extensive descriptions in the Company's Registration Statements and Annual Reports on Form 10-K filed from time to time with the Securities and Exchange Commission. In those statements and reports, the Company more extensively describes its products, markets, marketing and distribution efforts, manufacturing processes, government regulatory issues, competition, patents, management and management compensation.

3

#### RISK FACTORS

In evaluating a transaction in the Common Stock of the Company, investors should consider carefully, among other things, the following risk factors, as well as the other information contained in the Company's registration statements and reports filed with the Securities and Exchange Commission.

DEPENDENCE ON THIRD PARTY DISTRIBUTION ARRANGEMENTS;

## RISK OF PRICE EROSION

In recent years, the Company has steadily increased its sales to B.Braun/McGaw and its predecessor, McGaw, Inc. and Abbott Laboratories. During the same period, the Company has not increased its sales to its independent distributors that historically accounted for most of the Company's sales. As a result, the Company depends on fewer customers for a higher percentage of its sales than in the past. The table below shows the Company's sales to various types of customers for the first nine months of 1998, 1997 and 1996:

	Nine Months Ended		
	September 30,	Year Ended December 31,	
	1998	1997	1996
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B.Braun McGaw or predecessor	37%	36%	28%
Abbott Laboratories	27%	16%	7%
Independent distributors	36%	48%	65%

In contrast, the Company's principal competitors in the market for protective I.V. connection systems (including B.Braun/McGaw and Abbott) are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, the Company believes that there is a trend among individual hospitals and home healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit the Company's ability to gain market share through its

4

independent dealer network, resulting in continued concentration of sales among and dependence on a small number of customers.

B.Braun/McGaw and Abbott are major suppliers of I.V. products. The B.Braun/McGaw Agreement and the Abbott Agreement are strategic supply and distribution arrangements to market the Company's products in connection with each supplier's I.V. products. The Company's ability to maintain and increase its market penetration may depend on the success of its arrangements with B.Braun/McGaw, Abbott and major buying organizations and the ability to renew such arrangements, as to which there is no assurance. If the Company's independent distributorship or strategic supply and distribution arrangements prove unsuccessful, or if the Company's distributors abandon or limit their distribution of the Company's products, the Company's sales would be materially adversely affected. The Company's business could be materially adversely affected if B.Braun/McGaw or Abbott terminate their arrangements with the Company, negotiate lower prices, sell more competing products, whether manufactured by themselves or others, or otherwise alter the nature of their relationships with the Company. Although the Company believes that both B.Braun/McGaw and Abbott view the Company as a source of innovative and profitable products, there is no assurance that the Company's relationships with B.Braun/McGaw and Abbott will continue in their current form.

A significant share of the Company's revenues is concentrated among a small number of customers. If the Company loses any major customers or one of the Company's customers loses a large contract, the Company's operating results could be materially and adversely affected.

The Abbott Agreement and the B.Braun/McGaw Agreement establish the fixed prices that Abbott and B.Braun/McGaw will pay for the Company's products, which are lower than the Company's historical average selling prices. Furthermore, the Abbott Agreement and the B.Braun/McGaw Agreement provide for automatic reductions in minimum prices based on volume increases.

In response to competitive pressure, the Company has steadily reduced selling prices of the CLAVE to protect and expand its market. Management

expects that the Company will continue to reduce average selling prices. Reductions in average selling prices could adversely affect gross margins if the Company cannot achieve corresponding reductions in unit manufacturing costs through increased volume.

#### MARKET ACCEPTANCE OF PREMIUM PRICING; MANUFACTURING COSTS

Manufacturing costs and pricing for the Company's needleless and protected needle products are higher than for their conventional counterparts that are not designed

5

to provide the protection afforded by the Company's products. Selling prices of CLAVE system components are also higher than other competitive needleless systems on a per unit basis. The Company believes that the CLAVE can be cost effective on an actual use basis, but prospective customers must be convinced to pay premium prices for CLAVE products.

The Company's new products, the CLC 2000 and the lo2 Valve, and other new products under development will also cost more to manufacture than the existing devices they are designed to replace, and the Company will charge higher prices for such new products than customers would pay for conventional devices. As with the CLAVE, the Company believes that its new products offer advantages and potential cost savings in actual use that will offset their higher selling prices. The Company will, however, have to convince customers to pay premium prices for its new products.

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payors to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for the Company to sell its products at premium prices. In the event that the market will not accept premium prices for the Company's products, the Company's sales and profits could be adversely affected. The Company believes that its ability to increase its market share and operate profitably in the long term may depend in part on its ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If the Company is unable to reduce unit manufacturing costs, it may be unable to increase its market share for CLAVE products or lose market share to alternative products, including competitors' products or the Company's less expensive products such as the RF100 and RF150. Similarly, if the Company cannot reduce unit manufacturing costs of new products as production volumes increase, it may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect the Company's future results of operations.

#### DEPENDENCE ON CLAVE PRODUCTS; NEW PRODUCT DEVELOPMENT

During the nine months ended September 30, 1998, CLAVE products accounted for approximately 69% of the Company's net sales. As the demand for protective I.V. connection systems moved from protected needle to needleless products, net sales of the Company's Click Lock, Piggy Lock and B.Braun/McGaw protected needle products declined from approximately 50% of net sales in 1994, to approximately 9% of net sales in the nine months ended September 30, 1998.

The decline in protected needle product sales was offset in part by CLAVE product sales which increased from approximately 45% of net sales in 1994 to

6

approximately 69% of net sales for the nine months ended September 30, 1998, and in part by sales of other products and other sources of revenue, such as Lopez Valve, RF100 and RF150, BMP products and B.Braun/McGaw Safeline Revenue Sharing. The Company depends heavily on sales of CLAVE products, and the Company expects sales of protected needle products to continue to decline both in dollar volume and in relation to net sales.

The Company believes that sales of CLAVE products will continue to increase in the foreseeable future. It cannot, however, give any assurance that sales of CLAVE products will continue to increase indefinitely or that current profit margins on CLAVE products can be sustained indefinitely. Management believes

that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline as the Company loses market share, and/or the Company could encounter sustained price and profit margin erosion.

The Company's continued success may be dependent on new product development and on the development of technology systems and manufacturing, assembly and distribution systems for BMP that will enable it to develop significant market share on a profitable basis. Although the Company is seeking to develop a variety of new products, there is no assurance that any new products will be commercially successful or that the Company will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers with financial and distribution resources substantially greater than the Company's have developed and are marketing products intended to fulfill the functions of the Company's products. The ability of BMP to acquire significant market share on a profitable basis depends on whether the Company is able to develop systems capabilities, improve manufacturing efficiencies, lower inventory carrying costs, reduce labor costs and expand distribution. The accomplishment of each of these objectives will require significant innovation, and the Company cannot assure that it will succeed in these endeavors.

#### RISKS OF TECHNOLOGICAL OBSOLESCENCE

Many companies are developing products and technologies to address the need for safe and cost effective I.V. connection systems. It is possible that others may develop superior I.V. connection system technologies or alternative approaches that prove superior to the Company's products. The Company's products could become obsolete as a result of such developments, which could materially and adversely affect the Company's operating results.

7

#### INTENSE COMPETITION

The market for I.V. products is intensely competitive. The Company believes that its ability to compete depends upon its continued product innovation, the quality, convenience and reliability of its products, access to distribution channels, patent protection and price. The ability of BMP to compete will depend on its ability to distinguish itself from the competition based on product pricing, quality and rapid delivery. The Company encounters significant competition in this market both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of the Company's current and prospective competitors have economic and other resources substantially greater than the Company's and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that the Company's competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with the Company's products. The successful implementation of such a strategy by one or more of the Company's competitors could materially and adversely affect the Company.

#### DESIGN, MANUFACTURING AND ASSEMBLY RISKS

The Company manufactures substantially all of its product components, except for standard components which are available as commodity items, and assembles them into finished products. Automated assembly of components into finished products involves complex procedures requiring highly sophisticated assembly equipment which is custom designed, engineered and manufactured for the Company. As a result of the critical performance criteria for its products, the Company has at times experienced problems with the design criteria for or the molding or assembly of its products. While the Company believes that it has resolved all design, manufacturing and assembly problems with respect to current products, there is no assurance that operations will not be adversely affected

by unanticipated problems with current products or if such problems are experienced with future products.

The Company's BMP products do not have any inherent competitive advantage over other competitor's products. The Company believes that the success of its BMP operations will depend on its ability to lower per unit manufacturing costs and price its products substantially below its competitors' prices and on its ability to shorten significantly the time from customer order to delivery of finished product. To reduce costs, the Company will move BMP's labor intensive assembly operations to a facility it

8

is building in Ensenada, Baja California, Mexico. To shorten delivery times, the Company is developing proprietary systems for order intake, materials handling, tracking, labeling and invoicing and innovative procedures to expedite assembly and distribution operations. Many of these systems and procedures are new and innovative, and the Company cannot assure that any or all of them will succeed.

#### DEPENDENCE ON KEY EMPLOYEE

The Company depends for new product concepts primarily on Dr. George A. Lopez, the founder, Chairman of the Board, President and Chief Executive Officer of the Company. Dr. Lopez has conceived of substantially all of the Company's current and proposed new products and the systems and procedures to be used by BMP. The Company believes that the loss of his services could have a material adverse effect on the Company's business.

#### DEPENDENCE ON AND RISKS RELATING TO PATENT PROTECTION

The Company has patents on certain products and pending patent applications on others, including the CLC 2000 and the lo2 Valve and additional patents on some of its earlier products. There is no assurance, however, that patents will issue with respect to the CLAVE or other products, or that the patent protection from patents which have issued or may issue in the future will be broad enough to prevent competitors from introducing similar devices, that such patents, if challenged, will be upheld by the courts or that the Company will be able to prove infringement and damages in litigation.

The Company is not aware of any patent infringement claims against the Company relating to the Click Lock or the CLAVE, but the Company from time to time receives newly issued patents on medical devices which it reviews to evaluate any infringement risk. The Company is aware of a number of patents for I.V. connection systems that have been issued to others. While the Company believes these patents will not affect its ability to market its products, there is no assurance that these or other issued or pending patents might not interfere with the Company's right or ability to manufacture and sell its products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to the Company or to defend the Company against claimed infringement of the rights of others, can be expensive and may involve a substantial commitment of the Company's resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject the Company to significant liabilities to third parties, could require the Company to seek

9

licenses from third parties, could prevent the Company from manufacturing and selling its products or could fail to prevent competitors from manufacturing products similar to the Company's. Any of these results could materially and adversely affect the Company's business.

#### GOVERNMENT REGULATION

Government regulation is a significant factor in the development, marketing and manufacturing of the Company's products. The Company's products are subject to clearance by the United States Food and Drug Administration ("FDA") under a

number of statutes including the Food, Drug and Cosmetics Act. Each of the Company's current products has qualified, and the Company anticipates that any new products it is likely to market will qualify, for clearance under the FDA's expedited premarket notification procedure pursuant to Section 510(k) of the Food, Drug and Cosmetics Act. There is no assurance, however, that new products developed by the Company or any manufacturers that the Company might acquire will qualify for expedited clearance rather than a more time consuming premarket approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, the Company must manufacture its products in compliance with the FDA's Quality System Regulations.

The FDA has broad discretion in enforcing the Food, Drug and Cosmetics Act, and noncompliance with the Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the FDA determines that the Company has seriously violated applicable regulations, it could seek to enjoin the Company from marketing its products or the Company could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect the Company's business.

To market its products in the European Community ("EC"), the Company must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, the Company must comply with the quality management standards of EN ISO 9001(08/94)/EN 46001 (10/93). Those quality standards are similar to the FDA's Quality System Regulations but incorporate the quality requirements for product design and development. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ("Medical Device Directive") and their applicable annexes. Those are regulations that

10

assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. The Company cannot assure that it will continue to meet the requirements for distribution of its products in Europe.

Distribution of the Company's products in other countries may be subject to regulation in those countries, and there is no assurance that the Company will obtain necessary approvals in countries in which it wants to introduce its products.

#### RISK OF PRODUCT LIABILITY

The use of the Company's products exposes it to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that the Company's products have resulted in injury could initiate product liability litigation seeking large damage awards against the Company. Costs of the defense of such litigation, even if successful, could be substantial. The Company maintains insurance against product liability and defense costs in the amount of \$5,000,000 per occurrence. There is no assurance that the Company will successfully defend claims, if any, arising with respect to products or that the insurance carried by the Company will be sufficient. A successful claim against the Company in excess of insurance coverage could materially and adversely affect the Company. Furthermore, there is no assurance that product liability insurance will continue to be available to the Company on acceptable terms.

#### GROWTH AND ACQUISITION RISKS

The Company intends to expand its marketing and distribution capability internally, by expanding its marketing staff and resources and possibly externally, by acquisitions both in the United States and foreign markets. The Company may also consider expanding its product offerings through acquisitions

of companies or product lines. The Company will also move some assembly operations to Mexico and consider developing or contracting for manufacturing in Europe to eliminate transportation and other costs of shipping finished products from the U.S. to Europe. The expansion of the Company's manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on the Company's management resources and financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control. There is no assurance that the increasing burdens on the Company's management resources and financial controls will not adversely affect the Company's operating results. In addition, acquisitions may involve a

11

number of special risks, including adverse short-term effects on the Company's reported operating results, diversion of management's attention, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect the Company's operations and financial performance.

#### STOCKHOLDER RIGHTS PLAN; ANTI-TAKEOVER PROVISIONS

On July 15, 1997, the Board of Directors of the Company adopted a Stockholder Rights Plan (the "Plan") and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of Company Common Stock to stockholders of record at the close of business on July 28, 1997. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, no par value, at a Purchase Price of \$50 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board a great deal of flexibility in dealing with any attempted takeover of the Company and will cause persons interested in acquiring the Company to deal directly with the Board, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire the Company. Investors should refer to the description of the Plan in the Company's Current Report to the Securities and Exchange Commission on Form 8-K dated July 15, 1997 and the terms of the Rights set forth in a Rights Agreement between the Company and Chase Mellon Shareholder Services, L.L.C., as Rights Agent, which is filed as an exhibit to the July 15, 1997 Form 8-K.

The Company's Certificate of Incorporation and Bylaws include provisions that may discourage or prevent certain types of transactions involving an actual or potential change of control of the Company, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices. In addition, the Board of Directors has the authority to issue shares of Preferred Stock and fix the rights and preferences thereof, which could have the effect of delaying or preventing a change of control of the Company otherwise desired by the stockholders.

#### VOLATILITY OF STOCK PRICE

The market for small-market capitalization companies can be highly volatile, and the Company has experienced significant volatility in the price of its Common Stock in the past. The Company believes that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts expectations and actual quarterly and annual results, new product introductions by the Company or its competitors, changing regulatory environments, changes in healthcare reimbursement policies, sales of Common

12

Stock by certain existing stockholders and substantial product orders could contribute to the volatility of the price of the Company's Common Stock. General economic trends unrelated to the Company's performance such as recessionary cycles and changing interest rates may also adversely affect the market price of the Company's Common Stock.



Many older computer programs and systems use only the last two digits to refer to a year. Therefore, they do not properly recognize a year that begins with "20" rather than "19." This is referred to as the Year 2000, or Y2K Problem. The Y2K problem has been eliminated in many new programs and systems, which are said to be "Y2K compliant." The Company is engaged in investigations to determine whether its information technology ("IT") systems and non-IT systems (principally, manufacturing equipment and systems) are Y2K compliant and the consequences, if any, of non-compliance. The Company will also assess the extent of the Y2K readiness of third parties with whom the Company deals, such as suppliers, vendors, service providers, utilities, financial institutions, government agencies and customers and the possible consequences to the Company if such third parties are not Y2K compliant. Depending on the outcome of its investigations and assessments, the Company will consider developing a contingency plan to offset the effects of its or third parties' Y2K problems. The Company will report in its Annual and Quarterly Reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission on the status and costs of its investigations and remediation efforts, if any.

If some of the Company's IT and non-IT systems or those of third parties with whom it deals are not Y2K compliant, the Company could experience a number of consequences, including among others:

- . inability to receive and process orders;
- . inability to track production and distribution of products;
- . inability to invoice customers;
- . inability verify operating and financial information and prepare accurate reports;
- . interruptions in manufacturing operations;
- . corruption of internal and external bank and financial records;
- . interruptions in deliveries of services, materials and supplies; and
- . interruptions in payments from customers.

Any of the foregoing consequences, as well as others which the Company cannot anticipate, could materially and adversely affect the Company's operations, results of operations and financial condition. Further, the Company cannot assure that any contingency plan that it might develop would succeed in limiting the effects of Y2K

13

problems. In addition, various commentators have predicted widespread chaos in financial and other markets, interruptions in government programs and services, civil unrest and other consequences resulting from Y2K problems, generally. Such events could materially and adversely affect the Company's operations, results of operations and financial condition, regardless of whether it and the third parties with whom the Company deals are Y2K compliant.

#### 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, in the City of San Clemente, State of California on November 5, 1998.

ICU MEDICAL, INC.

By: /s/ Francis J. O'Brien

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Francis J. O'Brien  
Chief Financial Officer

14