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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 14, 1996

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

Delaware	0-19974	33-0022692
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

951 Calle Amanecer
San Clemente, California 92673
(Address of principal executive offices) (Zip Code)

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

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ITEM 5. OTHER EVENTS.

In reports and registration statements filed by ICU Medical, Inc. (the "Company") with the Securities and Exchange Commission and in communications by the Company with its stockholders and the investing public, the Company from time to time makes forward looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward looking statements involve a number of risks and uncertainties. The following is a summary description of the Company, followed by certain risk factors which investors should carefully read and consider when evaluating such forward looking statements.

THE COMPANY

The Company develops, manufactures and sells proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. 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. In 1993, the Company launched the CLAVE(R), a one-piece, needleless I.V. connection device which became the Company's fastest growing product. The Company believes that the CLAVE offers healthcare providers an advantageous combination of safety, ease of use, reliability and cost effectiveness.

The Company has entered into strategic supply and distribution agreements with two of the largest worldwide suppliers of I.V. products, McGaw, Inc. ("McGaw") and Abbott Laboratories ("Abbott"). Such agreements, entered into in September 1993 and April 1995, respectively, provide for the integration of the Company's products as components in certain prepackaged I.V. sets distributed by McGaw and Abbott. Under these agreements, McGaw and Abbott can offer such integrated products to large hospitals, hospital chains and home healthcare providers with which they have established full-line supply contracts for I.V.

products. In May 1995, the Company amended its agreement with McGaw and extended the term of such agreement to July 2000. The initial term of the Company's agreement with Abbott extends to April 2002. In addition, the Company has agreements under which its products are marketed to members of two major buying organizations. 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 needlesticks occur, have led to growing demand for safe medical devices such as the Company's protective I.V. connectors. In addition, healthcare regulations promulgated by the Occupational Safety and Health Administration ("OSHA") mandate that "universal precautions" be observed to minimize exposure to blood and body fluids.

The Company's products offer various combinations of features including needleless or enclosed needle connection systems, positive locking mechanisms and closed tubing systems and the Lopez Valve, which is designed to be connected into nasogastric tube systems to prevent

contact with body fluids in anteral feeding procedures. The Company has several new products under development, including a new version of the CLAVE. The Company has patents or pending patent applications on each of its current products.

The foregoing summary description of the Company is qualified by reference to 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. Those more extensive descriptions include more detailed discussions of the Company's products, markets, marketing and distribution efforts, manufacturing processes, government regulatory issues, competition, patents, management and management compensation.

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

The Company's products historically have been distributed to acute care hospitals, home healthcare providers, ambulatory surgical centers, nursing homes, convalescent hospitals, physicians' offices, medical clinics, emergency services and pharmacies primarily through independent distributors. In contrast, the Company's principal competitors in the market for protective I.V. connection systems are much larger companies which 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 and home healthcare providers to supply 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 independent dealer network.

The Company has entered into strategic supply and distribution arrangements with McGaw and Abbott, major suppliers of I.V. products, to market the Company's products in connection with each supplier's I.V. products. The Company also has agreements with remaining terms ranging from month-to-month to one year, to market products to members of two major buying organizations. Those arrangements with major buying organizations are expected to transfer to McGaw or Abbott on expiration. The Company's ability to maintain and increase its market penetration may depend on the success of its arrangements with 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 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 McGaw and Abbott view the Company as a source of innovative and profitable products, there is no assurance that the Company's relationships with 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. The loss of any such customers or the loss of a large contract by one of the Company's customers, could materially and adversely affect its operating results.

The Company's strategic supply and distribution agreements with Abbott (the "Abbott Agreement") and with McGaw (the "McGaw Agreement") establish the minimum respective prices that Abbott and McGaw will pay for the Company's products, which are lower than the Company's historical average selling prices. The Company could receive more than the minimum prices under formulae in the agreements based on incremental increases in selling prices of Abbott and McGaw I.V. sets incorporating the Company's products. Furthermore, the Abbott Agreement provides for annual renegotiation of minimum prices, and the McGaw Agreement, as amended, provides for automatic reductions in minimum prices based on volume increases. In response to competitive pressure felt in the third quarter of 1996, the Company in mid-October 1996 announced to its distributors a new aggressive pricing strategy to protect and expand its market. Prices to independent distributors will be reduced up to 40%, depending on the type of customer to which the distributor is reselling the CLAVE products. Management expects that the average price reduction in the fourth quarter of 1996 will be less than the maximum 40%, although the average price of its CLAVE products will decline over the next several quarters. 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, which are not designed 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. While the Company believes that the CLAVE can be cost effective on an actual use basis, prospective customers must be convinced to pay premium prices for CLAVE 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 affect the Company's ability 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 CLAVE 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 alterative products, including products of competitors or the Company's less expensive products such as the RF100 and RF150. Such a result would adversely affect the Company's future results of operations.

DEPENDENCE ON CLAVE PRODUCTS; NEW PRODUCT DEVELOPMENT

During the three months ended September 30, 1996, CLAVE products accounted for approximately 67% 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 and Piggy Lock protected needle products declined from approximately 93% of net sales in 1992, to approximately 11% of net sales in the three months ended September 30, 1996.

Although the decline in Click Lock and Piggy Lock sales was offset in part by sales of McGaw Protected Needles as the Company began manufacturing substantially all of McGaw's requirements for those products, sales of McGaw Protected Needles began to decline in the latter half of 1995, and the Company

anticipates further declines as demand continues to shift toward needleless products. The shift in demand from protected needle devices to needleless systems has increased the Company's dependence on sales of CLAVE products, as sales of the Company's protected needle products are expected to continue to decline both in dollar volume and in relation to net sales. Further, the Company's current product development efforts are centered primarily on a new version of the CLAVE. Sales of this new product will depend on continued market acceptance of CLAVE technology and may further increase the Company's dependence on the CLAVE system.

The Company's continued success may be dependent on new product development. 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.

RISKS OF TECHNOLOGICAL OBSOLESCENCE

Many companies are engaged in the development of products and technologies to address the need for safe and cost effective I.V. connection systems. There is no assurance that superior I.V. connection system technologies will not be developed or that alternative approaches will not prove superior to the Company's products. The Company's products could be rendered obsolete by such developments, which could materially and adversely affect the Company's operating results.

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 and patent protection. 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, and at least five major competitors have introduced needleless I.V. connection systems. 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 have a material adverse effect on 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. As a result, the Company has from time to time been unable to satisfy customer demand for new products as design, manufacturing or assembly problems were being resolved. 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.

DEPENDENCE ON KEY EMPLOYEE

The Company is dependent 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. 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 CLAVE. There is no assurance, however, that patents will be issued with respect to the CLAVE or other products, or that the patent protection from patents which have been issued or may be issued in the future will be broad enough to prevent competitors from introducing similar devices or that such patents, if challenged, will be upheld by the courts. 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 licenses from third parties and could prevent the Company from manufacturing and selling its products, any of which could have a material adverse effect on the Company's business. The Company is the plaintiff in currently pending patent litigation against Tri-State Hospital Supply Corporation which is described in the Company's current and annual reports filed with the Securities and Exchange Commission.

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 Federal Food, Drug and Cosmetics Act (the "FDC 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 FDC 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 ("PMA") 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's products must be manufactured in compliance with Good Manufacturing Practices ("GMP") specified in regulations under the FDC Act. The FDA has broad discretion in enforcing the FDC 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 there are serious violations of applicable regulations, marketing of products manufactured by the Company could be enjoined or 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. Distribution of the Company's products in countries other than the U.S. 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 claims arising with respect to products will be successfully defended or that the insurance carried by the Company will be sufficient. A successful claim against the Company in excess of insurance coverage could have

a material adverse effect on 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 expansion of the marketing, distribution and product offerings of the Company both internally and through acquisitions may place substantial burdens on the Company's management resources and financial controls. There is no assurance that the increasing burdens on the Company's management resources and financial controls will not have an adverse effect on the Company's operating results. In addition, acquisitions may involve a 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 have a material adverse effect on the Company's operations and financial performance.

ANTI-TAKEOVER PROVISIONS

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 12 months. 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 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.

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 14, 1996.

ICU MEDICAL, INC.

By: /s/ Francis J. O'Brien

Francis J. O'Brien
Chief Financial Officer