

SECURITIES AND EXCHANGE COMMISSIONS

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 27, 2001

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

(949) 366-2183

N/A

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

INFORMATION TO BE INCLUDED IN THE REPORT

Item 5. Other Events

On February 27, 2001, ICU Medical, Inc. and Abbott Laboratories signed the following agreement, as further described in the press release filed as Exhibit 2 hereto: "Co-Promotion and Distribution Agreement Between ICU Medical, Inc. and Abbott Laboratories."

Item 7. Financial Statements and Exhibits

(c) Exhibits

1. CO-PROMOTION AND DISTRIBUTION AGREEMENT, dated as of February 27, 2001.
2. Press release, dated February 28, 2001, announcing expansion of contract with Abbott Laboratories.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

Date: March 7, 2001

ICU MEDICAL, INC.

By: /S/ Francis J. O'Brien

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

CO-PROMOTION AND DISTRIBUTION AGREEMENT

THIS AGREEMENT is made this 27th day of February, 2001 ("Effective Date") by and between Abbott Laboratories, an Illinois corporation having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500 ("Abbott") and ICU Medical, Inc., a Delaware corporation having its principal place of business at 951 Calle Amanecer, San Clemente, California 92673 ("ICU").

WITNESSETH:

WHEREAS, ICU develops, manufactures and sells medical equipment such as intravenous ("I.V.") sets, connectors and other devices including needleless I.V. administration systems;

WHEREAS, ICU develops and manufactures I.V. sets ("Products" as hereinafter defined) for Customers (as hereinafter defined);

WHEREAS, ICU and Abbott entered into a Supply and Distribution Agreement dated April 3, 1995, as amended, for the distribution of certain ICU connector products ("Distribution Agreement");

WHEREAS, ICU wishes to expand its sales of Products through an additional distribution arrangement;

WHEREAS, Abbott, through its Hospital Products Division ("HPD"), is engaged in the development, manufacture, marketing and distribution of medical products and equipment;

WHEREAS, Abbott desires to become a distributor of Products in the Territory (as hereinafter defined);

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WHEREAS, in accordance with the terms and conditions hereof, ICU is willing to appoint Abbott as a distributor of Products, and Abbott is willing to accept such appointment; and

WHEREAS, Abbott and ICU also desire to engage in a transition period of no more than ninety (90) days, during which Abbott and ICU shall perform their duties and obligations under this Agreement in a limited region of the Territory.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, and upon the terms and subject to conditions set forth below, Abbott and ICU hereby agree as follows:

ARTICLE 1 - DEFINITIONS

The following words and phrases, when used herein with initial capital letters, shall have the meanings set forth or referenced below:

- 1.1 "ACT" shall mean the Federal, Food, Drug and Cosmetic Act, as amended, and all regulations promulgated thereunder.
- 1.2 "AFFILIATE" shall mean, with respect to each Party (as hereinafter defined), any legal entity that is, directly or indirectly, controlling, controlled by or under common control with such Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, more than fifty percent (50%) of the voting equity of the other entity (or other comparable ownership interest for an entity other than a corporation).
- 1.3 "BUSINESS DAY" shall mean any day other than a day which is a Saturday or Sunday or other day on which commercial banks in New York, New York are authorized or required to remain closed.

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- 1.4 "CALENDAR QUARTER" shall mean a period of three (3) consecutive calendar months commencing on January 1, April 1, July 1 or October 1 of any Contract Year (as hereinafter defined).
- 1.5 "CHANGE OF CONTROL EVENT" shall mean: (a) the consolidation or merger of ICU or any Affiliate of ICU with or into any Third Party (as hereinafter defined) wherein the shareholders of ICU immediately prior to such transaction shall cease to be the holders of at least fifty percent (50%) of the outstanding securities of the surviving corporation in such transaction; (b) the assignment, sale, transfer, lease or other disposition of all or substantially all of the assets of ICU; or (c) the acquisition by any Third Party or group of Third Parties acting in concert, of beneficial ownership (within the meaning of Rule 13d-3 of the Securities and Exchange Commission ("SEC") under the Securities and Exchange Act of 1934) of more than fifty percent (50%) of the outstanding shares of voting stock of ICU.
- 1.6 "CLAVE (R) PRODUCT" shall mean the following ICU devices: the CLAVE connector, the Integral CLAVE (also known as a "Y-CLAVE"), accessory products and any products incorporating a CLAVE or Integral CLAVE connector.
- 1.7 "CONFIDENTIAL INFORMATION" shall mean any and all technical data, information, materials and other know-how, including trade secrets, presently owned by or developed by, on behalf of, or derived either directly or indirectly from either Party and/or its Affiliates during the Term (as hereinafter defined) which relates to a Product, its development, manufacture, promotion, marketing, distribution, sale or use and any and all financial data and information relating to the business of either of the Parties and/or of their Affiliates, which a Party and/or its Affiliates discloses to the other Party and/or its Affiliates in writing and identifies as being confidential, or if

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disclosed orally, visually or through some other media, is identified as confidential at the time of disclosure and is summarized in writing within thirty (30) days of such disclosure and identified as confidential, except any portion thereof which:

- (a) is known to the receiving Party and/or its Affiliates at the time of the disclosure, as evidenced by its written records;
 - (b) is disclosed to the receiving Party and/or its Affiliates by a Third Party having a right to make such disclosure;
 - (c) becomes patented, published or otherwise part of the public domain through no fault of the receiving Party and/or its Affiliates;
 - (d) is independently developed by or for the receiving Party and/or its Affiliates without use of Confidential Information disclosed hereunder, as evidenced by its written records; or
 - (e) is required by law to be disclosed; provided, however, that no disclosure shall be made pursuant to this clause unless prior notice is given to the disclosing Party and the disclosing Party has a reasonable opportunity to prevent such disclosure or take appropriate preventive precautions relating to such disclosure.
- 1.8 "CONTRACT YEAR" shall mean a period of twelve (12) consecutive months during the Term of this Agreement, with the first Contract Year commencing on the first day of the month following the Effective Date. The initial Contract Year shall be from the Effective Date until December 31, 2001.

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- 1.9 "COST" shall mean ICU's Fully Burdened Manufacturing Cost (as hereinafter defined) plus outbound freight charges, as described in Section 7.3.

- 1.10 "CUSTOMER" shall mean any end-user that is: (a) evaluating for purchase; (b) ordering; or (c) purchasing Products from Abbott for use in the Territory.
- 1.11 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
- 1.12 "FULL LINE ACCOUNT" shall mean any Regular Abbott Purchaser (as defined in Section 2.5) and any Customer account for which Abbott holds the primary I.V. sets and solutions contract at the time of determination (i.e., Abbott supplies at least eighty percent (80%) of the account's I.V. sets (excluding proprietary pump sets) and solutions requirements).
- 1.13 "FULLY BURDENED MANUFACTURING COSTS" shall mean ICU's actually incurred cost to manufacture Product in accordance with QSR (as hereinafter defined) and Product Specifications (as hereinafter defined), including direct material, direct labor, yield losses, and an allocation for factory overhead related to Product including but not limited to the cost of line supervision, equipment depreciation, preventative maintenance, supplies, etc., pursuant to Section 7.3.. Such costs shall be determined following ICU's routine accounting practices applied consistently by ICU, provided that such accounting practices are in accordance with Generally Accepted Accounting Procedures ("GAAP").
- 1.14 "ICU DISTRIBUTORS" shall mean Third Parties that are authorized by ICU or an Affiliate of ICU to distribute Products in the Territory, pursuant to agreements, understandings or arrangements with ICU.

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- 1.15 "ICU SALES REPRESENTATIVE" shall mean an individual who is regularly employed by ICU on a full-time basis as a member of its sales force and who is qualified and has been trained by ICU to make sales presentations for ICU's device products to physicians and hospitals.
- 1.16 "ICU TRADEMARKS" shall mean the trademarks of ICU for Products or components of the Products as set forth on Exhibit 1.16.
- 1.17 "LIABILITIES" shall mean any claims, damages, losses, liabilities, debts or obligations of any nature, whether known or unknown, accrued, absolute, contingent or otherwise, and whether due or to become due.
- 1.18 "MARGIN" shall mean Net Sales (as hereinafter defined) minus the Cost of the Product sold to Customers.
- 1.19 "NET AVERAGE SELLING PRICE" OR "NET ASP" shall mean, for each Product, the Net Sales (as hereinafter defined) divided by the number of units of such Product shipped to Customers, inclusive of samples of each Product.
- 1.20 "NET SALES" shall mean the total of the gross amount billed or invoiced to Third Parties by Abbott for the sale of Product, less:
- (a) rebates granted and allowances, trade, quantity or cash discounts actually allowed and taken;
 - (b) fees, commissions or rebates lawfully paid pursuant to contracts with group purchasing organizations ("GPOs");
 - (c) amounts actually repaid a Third Party by reason of rejection or return of defective Products;

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- (d) upcharges invoiced and paid by Third Parties as part of rental agreement plans or similar arrangement; and
 - (e) wholesaler chargebacks, if applicable.
- 1.21 "PARTY" shall mean ICU or Abbott, and "PARTIES" shall mean ICU and Abbott.

- 1.22 "PRODUCT" shall mean SetSource(TM) I.V. Sets manufactured by ICU, which SetSource(TM) I.V. Sets may include proprietary products using Abbott's or ICU's proprietary devices or features, new configurations or non-proprietary pump sets, but SHALL NOT INCLUDE ANY proprietary pump set unless and until the Parties agree to include such product as a Product sold by Abbott hereunder. For the purpose of this Agreement the Lopez Valve(R) and the Bravo 24(TM) shall not be included in the definition of Product.
- 1.23 "PRODUCT SPECIFICATIONS" shall mean the written specifications and modifications thereto for each Product as such are specified by Customers for Product manufactured by ICU.
- 1.24 "PROMOTION EFFORTS" shall mean a sales presentation in the Territory, during which Products are promoted to Customers.
- 1.25 "PROMOTIONAL MATERIAL" shall mean printed matter, including printed literature and reprints, or graphic matter relating or referring to the Product useful in Promotion Efforts.
- 1.26 "QSR" or "QUALITY SYSTEM REGULATIONS" shall mean all current applicable standards relating to manufacturing practices for medical devices promulgated by the FDA in the form of laws, regulations or guidance documents (including, but not limited to, advisory opinions, compliance policy guides and guidelines) including current good manufacturing practices ("cGMP"), provided that with respect to any discretionary guidance documents, ICU knows or reasonably should have known that such guidance documents are applicable, currently feasible and valuable in ensuring device quality within the device manufacturing industry for such Products.

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- 1.27 "SETSOURCE(TM) I.V. SET" shall mean any I.V. set which is manufactured by ICU for sale by Abbott under this Agreement, provided that SETSOURCE(TM) I.V. SET shall exclude any I.V. set included in Abbott's or ICU's standard product catalog and exclude any existing non-catalog item of Abbott or ICU sold to Customers within the last six (6) months prior to the Effective Date. Abbott's non-catalog items are set forth on Exhibit 1.27 (a) and ICU's non-catalog items are set forth on Exhibit 1.27(b).
- 1.28 "TERM" shall mean the period beginning on the Effective Date and ending on December 31, 2009, or any extension thereto, unless otherwise terminated earlier in accordance with the terms and conditions of Article 11.
- 1.29 "TERRITORY" shall mean the United States (as hereinafter defined).
- 1.30 "THIRD PARTY" shall mean a natural person, corporation, partnership, trust, joint venture, limited liability company, governmental authority or other legal entity or organization other than the Parties and/or their Affiliates.
- 1.31 "TRANSFER PRICE" shall mean the price for Products purchased by Abbott and its Affiliates from ICU and its Affiliates hereunder, as more fully described in Section 7.3.
- 1.32 "UNITED STATES" shall mean the fifty (50) states of the United States, including the District of Columbia.

ARTICLE 2 - APPOINTMENT

- 2.1 APPOINTMENT IN FULL LINE ACCOUNTS. ICU hereby appoints Abbott as the exclusive distributor and co-promoter of the Products to Full Line Accounts in the Territory. During the Term, ICU shall not itself or through its Affiliates or Third Parties: (i) make sales of any Products

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to Full Line Accounts within the Territory (except for clinical trials

for regulatory approval); (ii) appoint or authorize any other distributor or sales representative to make sales of any Products to any Full Line Account within the Territory; or (iii) sell any Products to any entity that it knows or has reason to know will sell such Products to Full Line Accounts in the Territory, without Abbott's prior written permission unless pursuant to this Agreement, as set forth in Article 4. Abbott may, in its discretion, distribute, market and sell the Products to Full Line Accounts in the Territory through any Affiliate or wholly owned subsidiary of Abbott or use other general medical/surgical distributors in distributing, marketing and selling any Products in the Territory. Abbott shall have the right during the Term to represent to the public that it is the authorized exclusive independent distributor of the Products to Full Line Accounts within the Territory. Other than as expressly stated herein or agreed upon in writing between the Parties, ICU does not grant to Abbott exclusive distribution rights to any ICU proprietary devices.

2.2 APPOINTMENT IN THE TERRITORY. ICU hereby appoints Abbott as an authorized non-exclusive co-promoter and non-exclusive distributor of the Products to Customers other than Full Line Accounts in the Territory. During the Term, each Party may, through Third Parties: (i) make sales of any Product to Customers other than Full Line Accounts within the Territory; or (ii) appoint or authorize any distributor or sales representative to make sales of any Product to Customers other than Full Line Accounts within the Territory. Abbott may, in its discretion, market and sell the Products to Customers in the Territory through any Affiliate of Abbott or use other general medical/surgical distributors in distributing, marketing and selling any Product in the Territory. Abbott shall have the right during the Term to represent to

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the public that it is an authorized independent co-promoter and distributor of the Products to Customers other than Full Line Accounts within the Territory. In addition, upon the initial introduction of any product ICU decides to distribute through a Third Party, ICU shall grant to Abbott the right to distribute such ICU product upon such initial introduction of product into the market upon mutually agreed-upon terms, pursuant to Section 7.2.

2.3 SALES TO B. BRAUN MEDICAL, INC. ("BBM") ACCOUNTS. The provisions of paragraph 4.2 of the Supply and Distribution Agreement dated April 3, 1995, as amended by Amendment No. 8, dated the same day as this Agreement and attached hereto as Exhibit 2.3, shall apply equally to this Agreement.

2.4 DISTRIBUTORS. ICU shall notify ICU Distributors in Full Line Accounts in the Territory of Abbott's exclusivity, and shall use its best efforts to secure each ICU Distributor's agreement to honor Abbott's exclusivity. ICU shall use its best efforts to renegotiate any agreement, arrangement or understanding it has with ICU Distributors, on a commercially reasonable basis, to provide Abbott and its Affiliates with rights to exclusively distribute Products to Full Line Accounts in the Territory; PROVIDED, HOWEVER, that such best efforts shall not require that ICU terminate its agreements with entities that refuse to honor such exclusive rights.

2.5 FULL LINE ACCOUNTS. For the purposes of this Agreement, any Customer that purchases Product from Abbott pursuant to this Agreement shall be considered a Full Line Account for such specific Product upon such Customer becoming a "REGULAR ABBOTT PURCHASER" of such specific

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Product. For the purposes of this Agreement, a Customer shall be considered a Regular Abbott Purchaser of a specific Product for six (6) months after the Customer's initial order, or any subsequent order in the event such Customer ceased to be a Regular Abbott Purchaser subsequent to such Customer's initial order. A Customer shall continue to maintain such Full Line Account status for such Product if the Customer purchases such specific Product from Abbott in accordance with such Customer's regular purchasing pattern. For the purposes of this Agreement, any entity that purchases products substantially similar to

a Product from ICU or an Affiliate through an ICU Distributor shall be considered a "REGULAR ICU PURCHASER" of such product. A Regular ICU Purchaser of a specific product shall maintain its status as a Regular ICU Purchaser of such product for six (6) months after such entity's initial order, or any subsequent order in the event such entity ceased to be a Regular ICU Purchaser subsequent to such initial order, and shall continue to maintain such status for such product if the entity regularly purchases such specific product from such ICU Distributor.

2.6 NON-COMPETE. Neither Party may, without the agreement of the other Party, offer any Product for sale to any Customer if that Product is substantially similar to a product offered by either Party in such Party's standard product catalog or any existing non-catalog item sold to Customers within the last six (6) months. In no event shall this Section 2.6 be interpreted to prevent Abbott from submitting product bids or seeking new business with respect to Products.

ARTICLE 3 - ABBOTT'S RESPONSIBILITIES

3.1 ABBOTT'S DUTIES. Abbott shall use reasonable commercial efforts to introduce, promote the sale of, solicit and obtain orders for Products

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from Customers in accordance with the terms of this Agreement. Additionally, Abbott shall be responsible for all order entry, distribution, billing, collection of sales revenue, customer service support (excluding technical Product support) and processing of returns for the Products sold by Abbott to Customers in the Territory. In particular, Abbott shall assume the following responsibilities:

3.1.1 SALES AND MARKETING. Abbott shall assume responsibility for sales, marketing and product positioning activities for the Products to Full Line Accounts and its Customers pursuant to this Agreement in the Territory through HPD's commercial organization or another commercial organization, at Abbott's sole discretion. Abbott shall consult with ICU from time-to-time with respect to the manner in which Abbott shall promote the Products to Customers in the Territory. Except as otherwise expressly stated herein, Abbott shall be responsible for its own sales and marketing costs, which may include training and maintenance of its sales organization, formation of clinical symposia, promotion at appropriate trade shows, publication of promotional materials/reprints, and publication of appropriate journal advertisements.

3.1.2 CONTRACTING. Abbott shall be responsible for entering into all Customer contracts, including but not limited to, all hospital, GPO and Integrated Health Systems (IHS) sales contracts for the Products in the Territory.

3.1.3 PRICING AND PRICING STRATEGIES. Abbott, as exclusive distributor to Full Line Accounts and an authorized distributor to Customers in the Territory, shall solely and exclusively establish all prices and pricing strategies relating to the sale by Abbott of Products to Full Line Accounts and Customers in the Territory pursuant to this

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Agreement. Abbott will use commercially reasonable best efforts to establish prices within one (1) Business Day of request for Products. ICU Sales Representatives or other Abbott-authorized ICU personnel can present sales contract proposals for Products on Abbott's behalf to Customers including Full Line Accounts pursuant to this Agreement. In the event that an ICU Sales Representative or other Abbott-authorized ICU personnel desires to present a sales proposal for Products outside the prices established by Abbott, such ICU Sales Representative or Abbott-authorized ICU personnel shall contact HPD and shall obtain from HPD the

Product prices. Neither ICU nor any ICU Sales Representative nor other Abbott-authorized ICU personnel shall have the right to establish Product prices for sales made by Abbott to Customers hereunder.

- 3.1.4 REPORTS. Abbott shall provide sales reports to ICU which set forth sales activities by sales regions in the Territory in order to provide ICU with relevant information for compensating ICU Sales Representatives pursuant to Section 4.4.
- 3.1.5 TRANSITION PERIOD. The Parties agree that they shall participate in a transition period, during which the Parties shall commence the co-promotion activities contemplated by this Agreement in region(s) of the Territory identified by the Parties. Such transition period shall be from thirty (30) days to ninety (90) days in duration. Either Party shall have the right to request termination of the transition period at any time during the thirty (30) to ninety (90) day period; provided, that both Parties shall mutually agree to terminate such transition period. After the expiration or termination of the transition period, the Parties shall meet to assess such transition period and discuss implementation of the co-promotion of the Products in the entire Territory.

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- 3.2 COMMISSION. As consideration for ICU's performance of its sales and marketing obligations hereunder, Abbott shall pay ICU a commission pursuant to Section 7.5.
- 3.3 CUSTOMER CREDIT STATUS. Abbott shall notify ICU of any Customers placed on "credit hold" status by Abbott.
- 3.4 NO MINIMUM PURCHASE REQUIREMENTS. Nothing contained in this Agreement shall be construed to obligate Abbott to purchase any minimum quantity of any of the Products for sale to Customers including Full Line Accounts.
- 3.5 COMPLIANCE WITH LAWS. Subject to Article 4 below, Abbott shall, at all times during the Term, maintain any necessary legal permits and licenses required by any governmental unit or agency to distribute the Products hereunder and shall comply with all applicable national, state, regional and local laws and regulations, in performing its duties hereunder and in any of its dealings with respect to the Products as an independent distributor, except where the failure to obtain such permits or licenses or failure to comply will not have a material adverse effect on Abbott's ability to distribute the Products.

ARTICLE 4 - ICU'S RESPONSIBILITIES

- 4.1 APPOINTMENT. Abbott hereby appoints ICU to co-promote with Abbott the Products to Full Line Accounts in the Territory through the use of ICU Sales Representatives for the Term. ICU's duties shall include, but not be limited to, those set forth in this Article 4.
- 4.2 PRODUCT PROMOTION.
 - 4.2.1 GENERAL. During the Term, ICU, by and through ICU Sales Representatives, shall perform Promotion Efforts in the Territory in accordance with the terms of this Agreement. ICU shall consult with Abbott from time to time with respect to the manner in which ICU shall promote the Products to Customers in the Territory, including the indications for the

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Products and the frequency with which the ICU Sales Representatives shall perform Promotion Efforts to any particular Customer. ICU shall perform Promotion Efforts with respect to the Products only in strict accordance with: (i)

the approved Product labeling; and (ii) the applicable federal, state and local laws and regulations of the United States. As part of the Promotion Effort, and in accordance with Section 5.1.2 hereof, ICU Sales Representatives shall distribute Promotional Materials to Customers to whom the ICU Sales Representatives make Promotion Efforts and shall arrange for ICU's distribution of samples to Customers.

4.2.2 NUMBER OF PROMOTIONAL EFFORTS. During the Term, ICU, by and through the ICU Sales Representatives, shall use its commercially reasonable efforts to promote the Products for sale by Abbott to Customers. ICU, by and through ICU Sales Representatives, shall use commercially reasonable efforts to maintain Product usage profiles and monitor re-ordering. ICU shall prepare quarterly reports to Abbott summarizing its Promotion Efforts.

4.2.3 PRESENTATION OF CONTRACT PROPOSALS. ICU Sales Representatives shall have the right to present sales proposals for Products to Customers in the Territory. Such proposals shall be coordinated with HPD, and Abbott shall establish all Product pricing in connection therewith pursuant to Section 3.1.3. Sales proposals shall be signed by the ICU Sales Representative where indicated on the proposal, executed by the Customer, and accepted in writing by HPD in order to be effective. All sales for Products sold to Customers shall be through Abbott.

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4.2.4 SALES FORCE. At all times during the Term, ICU shall maintain a minimum sales force sufficient to fulfill its obligations hereunder.

4.3 CUSTOMER SERVICE. ICU shall use its best efforts to fill Customer or Abbott orders for Products that have been qualified by ICU as set forth on Exhibit 4.3. In the event that Product cannot be shipped according to the timeframe set forth on Exhibit 4.3, ICU shall inform Abbott and the appropriate Abbott sales representative or ICU Sales Representative at the time of contract proposal's preparation for a Customer that such order cannot be filled within the timeframe and of the underlying circumstances.

4.4 SALES REPRESENTATIVE TRAINING. ICU shall be responsible for training and supervising the ICU Sales Representatives in the promotion of the Product. At Abbott's request, ICU shall provide reasonable initial training of Abbott's personnel in the use of the Products.

4.5 ICU SALES REPRESENTATIVES' INCENTIVE COMPENSATION. For the Term, ICU, at its sole cost and at its sole discretion, shall award incentive compensation, bonuses or prizes to ICU Sales Representatives for achieving goals for volume of Abbott sales generated for the Products in such ICU Sales Representatives' sales territory. Pursuant to Section 3.14, Abbott shall supply certain sales information to aid ICU in the determination of incentive compensation related to the Products.

4.6 ADDITIONAL PRODUCTION CAPACITY. The Parties agree to jointly monitor expected production requirements for SetSource I.V. Sets, and to estimate whether such requirements will be within Aggregate Normal Deliveries (as defined in Exhibit 4.3). If such estimated requirements exceed Aggregate Normal Deliveries, ICU will make reasonable commercial efforts to meet such requirements.

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ARTICLE 5 - PROMOTION AND MARKETING ACTIVITIES

5.1 DEVELOPMENT AND DISTRIBUTION OF PROMOTIONAL MATERIALS.

5.1.1 PROMOTIONAL MATERIALS. Each Party shall provide the other Party with copies of all its technical, advertising and selling information and literature in English relating to

Product. Upon either Parties' request, the other Party shall furnish the requesting Party, at the requesting Party's cost, with reasonable quantities of technical, advertising and selling information and literature in English concerning the Products which the requesting Party may distribute, incorporate or include with its own marketing materials and information relating to the Products; provided, that neither Party shall have the right to use promotion material for any reason whatsoever EXCEPT in direct connection with such ----- Party's obligations to promote Product for sale by Abbott to Customers as set forth herein. If either Party determines that any Promotional Material conflicts with any law or regulation of the Territory, such Party shall inform the other Party of such determination as soon as reasonably possible, and the determining Party shall not be required to distribute such Promotional Material. If the other Party decides to use such Promotional Material, such Promotional Material shall be printed or reprinted, as the case may be, without the determining Party's logo or name thereon.

5.1.2 DISTRIBUTION OF PROMOTIONAL MATERIALS. In connection with the Promotion Efforts, the Parties shall distribute Promotional Materials to Customers with respect to the sale of Products by Abbott to Full Line Accounts and Customers. Each Party shall consult with the other Party with respect to the coordination of distribution of the Promotional Materials.

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5.1.3 MARKETING COSTS. Each Party shall pay all ordinary ordering and marketing costs it incurs. All extraordinary marketing costs with respect to co-marketing of Products for sale by Abbott to Customers hereunder will be incurred only after prior mutual written agreement of the Parties, and shall be shared between the Parties.

5.2 RESPONSIBILITY FOR SAMPLES. The Parties shall supply samples of Products to Customers in anticipation of sales by Abbott of Products to such Customers as part of Promotion Efforts hereunder and as the Parties mutually deem appropriate, to support Promotion Efforts. The Cost for such samples shall be an expense of the program and shared equally by the Parties.

5.3 REQUESTS FOR INFORMATION BY THIRD PARTIES. In the event Abbott's Medical Affairs Liaison described in Section 6.13.1 receives inquiries which relate to the efficacy, safety or other medical issues regarding the Product(s) from Third Parties, Abbott's Medical Affairs Liaison shall direct such inquiries within two (2) Business Days of such liaison's receipt of such inquiry to ICU's Medical Affairs Liaison described in Section 6.13.1, unless such inquiry is of a routine nature and the response is clearly set forth in the Product labeling. ICU shall provide Abbott on a quarterly basis with a summary of inquiries received relating to Products.

5.4 RESPONSIBILITIES OF ICU SALES REPRESENTATIVES. ICU Sales Representatives shall have the right, through their Promotion Efforts, to present Abbott contract proposals to Customers at prices established by Abbott and pursuant to Section 4.2.3. All such contracts shall be

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sent to Abbott at the following address: Abbott Laboratories Inc., HPD Contract Marketing, Attention: Manager, Major Accounts, D36J, AP30-2 Center, 200 Abbott Park Road, Abbott Park, IL 60064.

5.5 TRADE SHOWS. The Parties shall use reasonable efforts to co-promote the Product at trade shows and congresses pertinent to the Customers in the Territory. Such co-promotion efforts may include sharing of costs, provision of personnel and materials as well as joint exhibits, PROVIDED, that the Parties shall mutually agree to each Party's responsibilities and obligations prior to incurring any such costs or undertaking any responsibilities or obligations relating thereto.

ARTICLE 6 - MANUFACTURING, REGULATORY AND SAFETY

- 6.1 MANUFACTURING. ICU shall use reasonable commercial efforts to maintain adequate manufacturing capacity and sufficient means to produce the Products during the Term. Should ICU fail to maintain adequate manufacturing capacity of and/or sufficient means to produce the Products, ICU and Abbott shall in good faith use their reasonable commercial efforts to develop jointly a plan to ensure continued Product supply, which plan may include, at Abbott's reasonable discretion, Abbott's exercise of its standby right to manufacture the Products pursuant to Section 6.8.
- 6.1.1 WAREHOUSING OF ABBOTT COMPONENTS. The Parties shall negotiate in good faith the terms under which ICU shall warehouse Abbott components necessary for manufacture of Products at ICU's facilities during the Term of the Agreement.
- 6.1.2 ADDED PRODUCTION CAPACITY. If, in order to meet expected Abbott demand for Products during the Term of this Agreement, ICU determines that it is necessary to add production capacity which it would not add were it not solely for demand for the

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Products under this Agreement, ICU shall provide to Abbott information to support the necessity of such additional capacity and the Parties will consult and agree to terms concerning ICU's cost of the added production capacity.

- 6.2 FDA-APPROVED PLANT(S). ICU shall be considered to be the finished device manufacturer for the Products, and shall be responsible for compliance with all regulatory and safety testing requirements for the Products in the Territory. ICU shall maintain at all times during the Term of this Agreement an FDA-approved manufacturing plant(s) in which it shall manufacture all Products for Abbott in accordance with the Act and current Quality System Regulations and International Standards Organization ("ISO") certification. Abbott may, at its discretion, make QSR recommendations to ICU and ICU shall consider whether to implement any QSR recommendations made by Abbott. If ICU moves any finished product manufacturing of Products to a new location other than its current facilities in San Clemente, CA, or Ensenada, Baja California, Mexico, ICU shall notify Abbott at least thirty (30) days in advance of such move and allow Abbott to inspect such new manufacturing facilities pursuant to Section 6.4.
- 6.3 REGULATORY CLEARANCE AND REGISTRATIONS. ICU shall establish and maintain all regulatory clearances required to manufacture and permit the sale and distribution of Products in the Territory, including, at a minimum, all necessary FDA clearances for each Product. In the event that the inclusion of a device on a Product requires FDA 510(k) clearance, the Parties shall jointly evaluate the merits of incurring the cost of securing such regulatory clearance. If the Parties agree to proceed, the Parties shall share equally the costs involved in such clearance process. All such costs shall be estimated and agreed upon by the Parties in advance of incurring any costs.
- 6.4 INSPECTION OF FACILITIES. Prior to commencement of delivery of Products to Abbott hereunder, Abbott may, upon written notice to ICU, inspect ICU's manufacturing facilities to ensure that ICU's facilities, equipment and procedures meet applicable FDA regulations and QSRs. After such inspection, ICU shall notify Abbott of any material changes in its manufacturing facilities, equipment, procedures or raw materials necessary to manufacture Product. Such inspection right shall be in addition to Abbott's inspection rights pursuant to Section 6.5.
- 6.5 CONTINUING INSPECTIONS. From time to time during the term of this Agreement and no more than once per year (unless ICU receives any inspection notice or report from the FDA), Abbott may, upon written notice to ICU, inspect ICU's manufacturing facilities during normal

business hours to assure continued compliance of ICU's facilities, equipment and procedures with applicable FDA regulations and QSRs. ICU shall cooperate with Abbott in such inspections and provide necessary documentation and access to ICU's manufacturing facilities as may be reasonably required by Abbott.

- 6.6 COMPLIANCE WITH LAWS. ICU shall comply with all applicable state, federal and relevant international laws and regulations regarding the manufacture and delivery of Product, including but not limited to the Act and regulations relating to QSRs.
- 6.7 FDA INSPECTIONS. ICU shall advise Abbott immediately of the findings of FDA inspections and shall take all steps necessary to correct deficiencies found by the FDA relating to manufacturing of Product. ICU shall advise Abbott of any FDA compliance issues, including but not limited to, the receipt of FDA form 483 or any quality assurance problems with ICU's production facilities used in the manufacture of Product. ICU shall provide Abbott with copies of all such reports issued by the FDA as such relate to Products, shall provide Abbott with all responses to the FDA, and shall consider all Abbott's comments relating to any response.

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- 6.8 FAILURE TO SUPPLY. If ICU is unable to deliver Product in accordance with the terms of this Agreement, ICU shall authorize Abbott to manufacture Product at Abbott's facilities or at Abbott's designated Third Party manufacturer's facilities and shall cooperate with Abbott as reasonably required to facilitate either Abbott's or a Third Party's manufacture of Product. In such event, ICU and Abbott shall share profits earned by Abbott from the sale of Product or components manufactured by Abbott after taking into consideration all additional costs incurred by Abbott in the manufacture of such Products or components. At such time as ICU is able to resume delivery of Products, the Parties shall promptly negotiate an equitable arrangement in good faith regarding the manufacture of Product by ICU to meet Abbott's requirements taking into account Third Party agreements and arrangements. In no event shall Abbott be required to manufacture Product for sale or distribution by any Third Party.
- 6.9 POST-MARKETING REGULATORY REPORTING. ICU shall be responsible for reporting any reportable events, including but not limited to, patient deaths or injuries, associated with the Products to the FDA and other appropriate authorities; PROVIDED, HOWEVER, that to the extent required by applicable law Abbott may also report such events to the applicable authorities. Each Party shall notify the other Party of any such event within two (2) Business Days after the notifying Party learns of such an event. Each Party shall use reasonable commercial efforts to notify the other Party of any such event prior to notifying the FDA or other appropriate authorities. Each Party shall provide the other Party with any assistance reasonably requested by the other Party and considered necessary by the requesting Party in connection with reportable events, including without limitation access to the Product files.

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- 6.10 COOPERATION. To assist in selling and marketing the Products for sale by Abbott to Customers in the Territory, each Party shall, as applicable:
- (a) provide the other Party with any information reasonably requested by the other Party for the purpose of complying with regulatory and other legal requirements relating to the Products;
 - (b) provide the other Party with information on marketing and promotional plans for the Products as well as copies of marketing, advertising, sales and promotional literature concerning the Products, if any; and
 - (c) provide the other Party with certificates of free sale, trademark authorizations and any other

documents relating to the Products which the other Party may reasonably request to satisfy the requirements of the laws of the various jurisdictions within the Territory and of any competent authority.

- 6.11 PRODUCT CHANGES. ICU shall provide Abbott with at least thirty (30) days' prior written notice of any change to the processes, materials, equipment, inspection or testing of the Products of which it has knowledge that may have any effect on the Products or their uses.
- 6.12 INSPECTION AND APPROVAL OF PRODUCTS. Except for latent defects, Abbott shall, and shall insure that any Customer shall, have a period of thirty (30) days from the date of shipment to notify ICU that a Product delivered to Abbott or a Customer does not conform to Product Specifications. Abbott shall have the right to return any Product, or to have any Customer return any Product, that does not so conform. All

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or part of any shipment shall be held for ICU's disposition and at ICU's expense if found not to be in conformance with Product Specifications; PROVIDED, that ICU shall confirm such nonconformance through generally accepted quality control procedures. If a dispute arises as to whether a Product conforms to Product Specifications and the Parties are unable to resolve the dispute, the matter shall be referred to an independent Third Party testing laboratory agreed to by the Parties. The testing laboratory shall test the Product in question for conformance with Product Specifications and shall provide the results of its analysis to ICU and Abbott. The decision of the testing laboratory regarding conformance with Product Specifications shall be final and binding on the Parties. The cost of the testing laboratory shall be paid by the Party found to be in error. If Abbott and/or Customer do not reject a shipment within thirty (30) days after shipment by ICU, such shipment shall be deemed to have been accepted.

6.13 NOTIFICATION OF ADVERSE EVENTS.

- 6.13.1 COMMUNICATION. Within thirty (30) days after the execution of this Agreement, each Party shall appoint a primary liaison (the "MEDICAL AFFAIRS Liaison") to communicate with the other Party with regard to information required pursuant to Section 5.3 or 6.13.2. Either Party may change its Medical Affairs Liaison by notice to the other Party.
- 6.13.2 NOTIFICATION. During the Term of this Agreement, Abbott shall give ICU notice as set forth in this Section 6.13.2 of any medical device reportable event ("Event"), as defined in 21 CFR 804.3, associated with the Product as to which Abbott obtains information in accordance with the following:

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- (a) Any Event information obtained by Abbott shall be reported to ICU's Medical Affairs Liaison, by telephone or in writing (only by facsimile) within two (2) Business Days after Abbott's initial receipt of the information or as soon as practicable thereafter; PROVIDED, HOWEVER, any report of a serious injury or any report of a death shall be reported to ICU's Medical Affairs Liaison within twenty-four (24) hours of Abbott's receipt of the information. Abbott shall use reasonable commercial efforts to notify ICU prior to notifying the FDA or other appropriate authorities;
- (b) Abbott's reports to ICU shall contain the date the report was received by Abbott, and if possible: (i) the name of the reporter and the reporter's title; (ii) the address and telephone number of the reporter; (iii) a description of the adverse device experience; (iv) the indication for treatment; (v) the outcome of the event; (vi) the dose and duration of treatment; and (vii) the lot number of the

Product, if available; and

- (c) Abbott shall maintain a record of the Event, including: (i) a copy of the Event report; (ii) the date the Event report was received; (iii) the date the Event report was provided to ICU; and (iv) ICU's name and address.

6.13.3 EVENT REPORT. During the Term, if ICU determines it is necessary to issue a report to its representatives with respect to the medical efficacy or side effects of the Product(s), ICU shall also provide such report to Abbott as soon as possible, and the Parties will cooperate in an immediate and concurrent distribution of the report to the ICU Sales Representatives and to the Abbott sales representatives.

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6.14 RECALLS. A Party shall give prompt notice of any contemplated recall of any Products to the other Party (including notice by ICU to Abbott of any such recall outside the Territory). The Parties shall cooperate fully throughout the recall process whether such recall is voluntary or otherwise, and shall comply in full with applicable laws, regulations and governmental agency directives with respect to such recall. Any recall expenses incurred by the Parties resulting from either or both Party's deficiencies, Product quality defects, Product performance defects or government actions shall be paid by the Party responsible for the deficiency or defect.

6.15 LABELING OF PRODUCTS. Products sold to Customers by Abbott hereunder shall be labeled as manufactured by ICU and shall be marked with an Abbott list number and lot number pursuant to Section 8.5. All Product packaging shall be of the type normally and customarily used by ICU in its production process, and shall support the label claim(s).

6.16 QUALIFICATION OF COMPONENTS. Abbott shall provide ICU with samples and related information (such as, materials, biocompatibility information, etc.) with respect to all components that Abbott expects to use in Products for qualification purposes, in advance of orders to manufacture, in order to permit timely qualification of those components in ICU's manufacturing process.

6.17 PRODUCT COMPLAINTS. ICU shall be responsible for handling Customer complaints related to Product sold to Customers by Abbott hereunder. ICU shall receive, investigate and respond to all such complaints in a timely manner, and adhere to all regulations relative to complaint handling and reporting events to the FDA and other regulatory authorities. ICU shall provide a monthly report to Abbott containing: (a) all Customer complaints ICU received for that month with respect to any Products; (b) ICU's responses to such complaints; (c) all reports to regulatory agencies; and (d) the status of any previous Customer complaints still pending.

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ARTICLE 7 - FINANCIAL TERMS, PRODUCT ORDERS AND PRODUCT DELIVERY

7.1 OBLIGATIONS TO PURCHASE PRODUCTS. Abbott hereby agrees to purchase its requirements of Products in the Territory exclusively from ICU; PROVIDED, that: (a) Abbott shall not be required to purchase from ICU any I.V. set products that Abbott manufactures as of the Effective Date, but shall have the right to transition such products to ICU for manufacture, at Abbott's sole discretion; (b) Abbott shall have the right to seek alternative manufacturers and suppliers of I.V. set products or to have itself manufacture I.V. set products that ICU either cannot manufacture or manufactures at a cost that is not competitive with other similar products manufactured and/or supplied by Third Parties or itself; and (c) if Product can be manufactured by Abbott at a lower cost, the manufacturing of the Product shall be transferred to Abbott at Abbott's option. If Abbott exercises such option to manufacture Product(s) hereunder, the Parties agree to meet to determine the terms of such transfer or manufacturing prior to any such transfer of manufacturing to Abbott and agree to maintain the

commission structure and percentages as described in Section 7.5 and all other provisions of the Agreement except those related to ICU's manufacturing of Product.

- 7.2 RIGHT TO SELL AND DISTRIBUTE. In the event that ICU decides, in its sole discretion, to sell and distribute any new products through a Third Party, ICU shall grant to Abbott the right to sell and distribute

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any of such products upon the initial introduction of such products into the market; PROVIDED, that the Parties agree to contractual terms which are set forth in a separate agreement executed between the Parties.

- 7.3 TRANSFER PRICE TO ABBOTT. The Transfer Price to Abbott for each Product purchased by Abbott from ICU under this Agreement is set forth on Exhibit 7.3. In calculating the Fully Burdened Manufacturing Cost, ICU shall account for the following:

- (a) Components supplied and billed by Abbott to ICU at Abbott's standard cost, which shall approximate actual manufacturing costs, including material, direct labor, manufacturing overhead and yield losses, plus freight to ICU's manufacturing site; PROVIDED, that such standard costs shall be determined following Abbott's routine accounting practices applied consistently by Abbott, as long as such accounting practices are in accordance with GAAP;
- (b) Any proprietary components provided by Abbott to ICU shall be provided at a price agreed upon by the Parties;
- (c) Any proprietary components provided by ICU that are sold to Abbott under another agreement shall be included in the calculation as the amount specified in that agreement, or at an agreed-upon amount;
- (d) Any proprietary components supplied by ICU that are not sold to Abbott pursuant to Section 7.2 or under another agreement shall be included in the calculation at an agreed-upon amount.

ICU agrees that it shall not use components supplied by Abbott for use in Products or for any other products it manufactures or supplies, unless such use: (i) is agreed upon in writing by Abbott; or (ii) is permitted under a separate agreement between the Parties. In no event

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may any Product or any other ICU product incorporating Abbott components be sold or distributed by ICU or through any Third Party. For the purposes of this Section 7.3, ICU proprietary components shall mean the CLAVE Products, the CLC2000 and 1o2 Valve. The Transfer Price of the 1o2 Valve shall be as set forth on Exhibit 7.3.

- 7.4 SELLING PRICE. The price of Product sold by Abbott hereunder shall be determined solely by Abbott and shall reflect fairly the value of Products in the marketplace in the Territory. Any and all information provided by Abbott to ICU personnel shall be considered as Abbott's Confidential Information and shall be restricted to the ICU personnel primarily and directly responsible for working with Abbott relating to the Products.

- 7.5 COMMISSIONS. Net Sales of Products shall be calculated by Abbott on a Calendar Quarter basis for the first Contract Year, and on a monthly basis thereafter. Monthly calculations may be deferred based upon mutual agreement of the Parties. As consideration for ICU's performance of its sales and marketing obligations hereunder, Abbott shall pay ICU a commission based on a percentage of Margin, on a Calendar Quarter basis, calculated as follows: Net Price minus Cost shall equal Margin,

as illustrated in Exhibit 7.5 - Commissions. ICU's commissions or amount credited Abbott shall be equal to the amounts as indicated in Exhibit 7.5. At the end of each Calendar Quarter during the Term, a reconciliation shall be performed by Abbott, on a Product by Product basis, based on the actual Net Sales of such Products, the Transfer Price for each Product previously paid by Abbott to ICU and ICU's commission due on the Net Sales of the Products. The amount owed to ICU or credited to Abbott shall be the difference between the commission portion of the Transfer Price paid and the commission due and payable

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to ICU hereunder pursuant to this Section 7.5 (sample reconciliation illustrated in Exhibit 7.5 - ICU Margin Share Reconciliation). Abbott shall supply such reconciliation to ICU within thirty (30) days of the end of the Calendar Quarter of any difference calculated, and such difference shall be settled between the Parties within forty-five (45) days following the end of each such Calendar Quarter.

7.6 ORDER PLACEMENT.

7.6.1 PURCHASE ORDERS. All purchases of the Products by Abbott or Customer from ICU shall be made by written purchase order or EDI issued by or to Abbott. Such orders shall include the following information: Product type and Product Specifications, quantity, price, requested delivery schedule, delivery location, and shipping instructions. All purchases of the Products by Abbott from ICU during the Term shall be subject to the terms and conditions of this Agreement. Any additional or different terms and conditions in a purchase order or confirmation form which are additional to or which conflict with this Agreement shall be of no force and effect unless the Parties specifically agree in writing to such terms and conditions. Alternatively, Customers may directly forward to ICU purchase orders for Products issued to Abbott. In such case, ICU shall consider the purchase order as being generated by Abbott and shall provide a copy of such purchase order to Abbott.

7.6.2 ACCEPTANCE OF ORDERS. All orders and modifications to orders are subject to acceptance by ICU. ICU shall use commercially reasonable efforts to fill all orders by Abbott or its Customers for the Products hereunder. If ICU believes that it

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will not be able to satisfy Abbott's or Customer's orders for the Products pursuant to this Agreement, ICU shall notify Abbott and its Customer at the time of proposal, specifying the reasons for the delay and its expected duration. Once an order is placed by Abbott or its Customer and accepted by ICU, it cannot be canceled.

7.7 PRODUCT DELIVERY

7.7.1 TITLE AND RISK OF LOSS. Products shall be stored at ICU's facilities. Title and risk of loss to Product sold by Abbott to Customers hereunder shall transfer to Abbott upon final release of Product by ICU. Upon final release of Product by ICU, the quantity of Product subject to risk of loss shall be limited to the quantity of Product subject to existing purchase orders.

7.7.2 TAXES. Abbott shall pay all sales and similar taxes payable with respect to the sale and purchase of Products sold by Abbott to Customers under this Agreement, except for taxes based on ICU's income or importation duties.

7.7.3 SHIPPING INSTRUCTIONS AND CHARGES. All Products to be sold by Abbott to Customers hereunder shall be suitably packaged, packed for shipment and marked by ICU, for shipment to either: (a) Abbott's United States facilities; or (b) to the Customer, as designated in the purchase order. Upon Customer request for

expedited shipment of Product sold by Abbott hereunder, ICU shall have the right to ship Product using expedited means and recoup from Abbott shipping charges incurred over and above the amount built into the Transfer Price. ICU shall notify Abbott of any Customer request for expedited shipping at the time of ICU invoices to Abbott. Additional shipping charges

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are to be consistent with the policies set forth in Abbott's current product catalog. ICU shall be responsible for the difference between expedited shipping charges and routine shipping charges for certain shipments that are shipped on an emergency basis as described in Exhibit 4.3.

7.7.4 PARTIAL SHIPMENTS. ICU may make partial shipments against Abbott's or Customer's purchase orders.

7.8 ADDITIONAL ORDER REQUIREMENTS. The Parties agree to meet and determine an electronic interface system between Abbott and ICU to effect order status tracing of Products.

7.9 PAYMENT TERMS. Abbott shall pay to ICU within thirty (30) days of the full or partial shipment of Product an amount mutually agreed by the Parties for the Transfer Price for each Product as specified in Section 7.3 above and delivered to Abbott or Customer pursuant to this Agreement. Additionally, Abbott shall pay to ICU within forty-five (45) days of the end of each Calendar Quarter for the first Contract Year and monthly thereafter, an actual amount for the commission on Product sales during such Calendar Quarter as specified in Section 7.5.

7.10 INSPECTION OF RECORDS. Abbott and ICU shall have the right, either directly or through an independent certified accountant reasonably acceptable to the other Party, to audit each other's compliance with the financial provisions of the Agreement once per Contract Year at the inspecting Party's own expense, during normal business hours and upon at least ten (10) Business Days' notice to the inspected Party. If one Party finds that it is due an amount in excess of \$25,000 from the other Party as a result of such audit, then the inspected Party shall bear the expense of the audit. All individuals conducting such audit shall sign a non-disclosure agreement with the inspected Party on terms at least as stringent as those contained in this Agreement.

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7.11 RETURNS. Abbott shall be responsible for returns of Product sold by Abbott hereunder. Abbott may return for a refund any Product that does not meet ICU's warranty as set forth in Sections 9.1, 9.2 and 9.3 or if such Product is shipped by ICU in error. ICU shall issue a return goods authorization ("RGA") number for such defective Product upon Abbott's request. At ICU's expense, Abbott shall return any such defective Product to ICU with documentation referencing the applicable RGA number.

ARTICLE 8 - INTELLECTUAL PROPERTY

8.1 GENERAL. Each Party shall use reasonable commercial efforts to file, prosecute, protect and maintain its intellectual property rights (including patents, know-how and ICU Trademarks) relevant to the Products in the Territory at its own expense. If either Party becomes aware of any actual or potential Third Party infringement of such intellectual property rights or any Third Party claim that ICU's manufacture and sale of the Products to Abbott hereunder or Abbott's sale of Products to Customers infringes any Third Party intellectual property rights, such Party shall promptly notify the other Party.

8.2 TRADEMARK USAGE. Each Party shall obtain prior written approval from the other Party for each proposed usage of the other Party's trademark for any marketing or other promotional use relating to the Products. Such approval, if granted, shall only be for the specific usage requested.

8.3 OWNERSHIP OF ICU TRADEMARKS. Abbott acknowledges that, subject only to the license granted herein to Abbott, ICU owns and retains all proprietary rights in all ICU Trademarks.

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8.4 USE OF TRADEMARKS. Any use of either Party's trademark or trade name by the other Party shall be subject to the owning Party's prior written approval, which approval may be withheld by the owning Party at its sole discretion.

8.5 OWNERSHIP OF ABBOTT TRADEMARKS. Subject to Section 8.2, ICU acknowledges that Abbott owns and retains all proprietary rights in its trademarks.

8.6 NO CONTINUING RIGHTS. Upon termination of this Agreement, each Party shall cease all further display, advertising and use of all the other Party's Trademarks as such relate to Products except in connection with the sale of Products in inventory as provided in Section 11.5 below.

8.7 LOT NUMBERS AND LIST NUMBERS IN LABELING. Pursuant to Section 6.15, ICU shall mark each saleable unit of Product to be sold by Abbott to Customers hereunder with an Abbott list number and Abbott lot number printed on the label (the case label), and preferably, each individual unit of Product shall have list numbers and lot numbers using the Abbott numbering convention. Abbott shall supply ICU with Product list numbers, lot number suffixes and lot number blocks as soon as commercially feasible after the Effective Date.

ARTICLE 9 - WARRANTIES, REPRESENTATIONS AND INDEMNIFICATIONS

9.1 WARRANTY OF PRODUCTS BY ICU. ICU warrants and represents to Abbott that ICU has or is currently seeking FDA approval to market Products as approved devices under the Act. During the Term of this Agreement, ICU shall provide to Abbott copies of Sec. 510(k) approval letters pertaining to ICU products, FDA 483 manufacturing inspection reports,

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recall information and any other regulatory information as may be reasonably required by Abbott. ICU shall cooperate with Abbott to resolve any regulatory problems with the FDA to permit prompt marketing of Products or the continued marketing of Products. If requested by Abbott as a result of an FDA request for information, ICU shall authorize Abbott to refer to ICU Sec. 510(k) clearances relating to Products.

9.2 ICU PRODUCT GUARANTEES. ICU guarantees to Abbott that Product delivered pursuant to this Agreement shall at the time of delivery not be adulterated or misbranded within the meaning of the Act, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, as such Act and such laws are constituted and effective at the time of delivery and will not be an article which may not under the provisions of the Act be introduced into interstate commerce.

9.3 ICU PRODUCT WARRANTIES. ICU warrants that Product delivered to Abbott pursuant to this Agreement shall conform to Product Specifications and shall be manufactured in an FDA-approved facility in accordance with QSRs, including GMPs.

9.4 ABBOTT GUARANTEES. Abbott guarantees to ICU that Abbott's products delivered to ICU for incorporation in Products pursuant to this Agreement, at the time of delivery, shall not be adulterated or misbranded within the meaning of the Act, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the act, as such Act and such laws are constituted and effective at the time of delivery and will not be an

article which may not under the provisions of the Act be introduced into interstate commerce.

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- 9.5 ABBOTT WARRANTIES. Abbott warrants that Abbott products delivered to ICU for incorporation in Products pursuant to this Agreement shall be manufactured in an FDA-approved facility in accordance with QSRs including GMPs.
- 9.6 ABBOTT'S INDEMNIFICATION OF ICU. Abbott shall indemnify and hold ICU harmless from and against all Liabilities to the extent such arise out of or are attributable to: (a) any negligent or wrongful act or omission on the part of Abbott, its employees, agents or representatives; (b) any alleged infringement of any Third Party intellectual property right resulting from the manufacture, use, sale or importation of an Abbott component incorporated into Product; (c) a breach of Abbott's guarantees or warranties hereunder; or (d) the use of or lack of safety or efficacy of any Product to the extent that any such Liability is attributable to an Abbott component incorporated into Product.
- 9.7 ICU'S INDEMNIFICATION. ICU shall indemnify and hold Abbott harmless from and against all Liabilities, to the extent such arise out of or are attributable to: (a) any negligent or wrongful act or omission on the part of ICU, its employees, agents or representatives; (b) any alleged infringement of any Third Party intellectual property right resulting from the manufacture, use, sale or importation of Product; (c) any breach of any of its guarantees, warranties or representations hereunder; or (d) the use of or lack of safety or efficacy of any Product to the extent that any such Liability is not attributable to an Abbott component incorporated into Product.
- 9.8 NOTICE AND DEFENSE. The Party seeking indemnification shall promptly notify the other Party of any Liabilities for which indemnification is sought. The indemnified Party shall cooperate in the defense of any

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Liability and shall allow the indemnifying Party to control the defense of any such Liability. No settlement shall be made without the consent of the indemnifying Party.

- 9.9 GENERAL REPRESENTATIONS AND WARRANTIES. Each Party represents and warrants to the other Party as of the Effective Date, as follows:
- (a) It is a corporation duly organized and validly existing under the laws of its state of incorporation;
 - (b) It has the power and authority to execute and deliver this Agreement and to perform its obligations thereunder;
 - (c) The execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any other agreement or relationships.
- 9.10 REPRESENTATIONS, WARRANTIES AND COVENANTS OF ICU WITH RESPECT TO PRICING INFORMATION. ICU, with respect to itself and its Affiliates, hereby represents, warrants and covenants to Abbott and its Affiliates that it has not exchanged and will not exchange Abbott's Confidential Information including any Confidential Information relating to the prices or terms at which Abbott or its Affiliates will offer SetSource(TM) products for sale between or among any Third Party or their Affiliates, directly or indirectly, and it has not exchanged and will not exchange Abbott's Confidential Information between or among any employee, officer, agent or consultant of ICU or its Affiliates who is not primarily and directly responsible for working with Abbott relating to the Products and that ICU shall restrict such Confidential Information to ICU personnel primarily and directly responsible for

working with Abbott relating to the Products.

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- 9.11 NO EXCHANGE OF PRICING INFORMATION. The Parties hereto recognize and acknowledge that ICU and its Affiliates may be and may in the future be engaged, directly or indirectly, in activities that are competitive with Abbott. Accordingly, ICU and Abbott each understands and agrees that it will not exchange Abbott's Confidential Information between or among Third Parties or their Affiliates, or between or among any employee, officer, agent or consultant of ICU or its Affiliates that is not primarily and directly responsible for working with Abbott relating to the Products and only in direct connection with such employee's officer's, agent's or consultant's responsibilities under this Agreement. ICU also shall restrict such Confidential Information to ICU personnel primarily and directly responsible for working with Abbott relating to the Products.
- 9.12 EFFECT OF INFRINGEMENT CLAIMS. If a claim of patent or other proprietary right infringement is made by a Third Party with respect to a Product, then ICU, at its option, shall: (a) obtain for Abbott the right to continue to market and distribute the Product at ICU's own expense, (b) replace the Product with a functionally-equivalent non-infringing Product, or (iii) modify the Product so that it becomes non-infringing, so long as the functionality of the Product is not adversely affected. If ICU is unable to accomplish any of the foregoing within one hundred eighty (180) days of the initial claim of infringement, the Parties shall remove all such affected Products from the Agreement.
- 9.13 LIMITATION OF LIABILITY. EXCEPT FOR THE INDEMNIFICATION OBLIGATIONS HEREUNDER, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR OTHER DAMAGES (INCLUDING WITHOUT LIMITATION LOSS OF PROFITS) WHETHER OR NOT ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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ARTICLE 10 - CONFIDENTIALITY

- 10.1 NON-DISCLOSURE. It is recognized by the Parties that during the Term of this Agreement the Parties may exchange Confidential Information. Abbott agrees that it shall not disclose Confidential Information received from ICU, and shall not use Confidential Information disclosed to it by ICU for Abbott's benefit (other than in the performance of its obligations hereunder) or for the benefit of any Third Party. ICU agrees that it shall not disclose Confidential Information received from Abbott, and shall not use Confidential Information disclosed to it by Abbott for ICU's benefit (other than in the performance of its obligations hereunder) or for the benefit of any Third Party. Notwithstanding the above, nothing contained in this Agreement shall preclude ICU or Abbott from utilizing Confidential Information as may be necessary in prosecuting patent rights of the Parties, in obtaining governmental marketing approvals for Product, or in manufacturing, marketing, selling, or distributing Products pursuant to this Agreement. The obligations of the Parties relating to Confidential Information shall expire three (3) years after the termination of this Agreement.
- 10.2 TERMS OF AGREEMENT ARE CONFIDENTIAL. The Parties agree that the terms and conditions of this Agreement shall be considered confidential and shall not be disclosed by the Parties to any Third Party; PROVIDED, HOWEVER, upon request by any federal or state regulatory authority, a Party may provide to such federal or state regulatory authority a copy of this Agreement. The Party providing the copy shall so advise the other Party at the time such action is taken.

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- 10.3 CONFIDENTIAL TREATMENT. If it is determined that this Agreement must be disclosed publicly in filings with the U.S. Securities and Exchange Commission (SEC) and any other governmental agency or self-regulatory

organization to which a copy of this Agreement must be provided, the Party making the disclosure to the SEC shall so advise the other Party, and shall request confidential treatment for the terms and conditions of this Agreement under exceptions to the Freedom of Information Act and SEC rules regarding confidentiality of information filed under the SEC's disclosure and reporting requirements to the fullest extent permitted by the SEC or other governmental agency or self-regulatory organization. Prior to seeking confidential treatment from the SEC or other governmental agency or self-regulatory organization, the disclosing Party shall provide the other Party with a copy of the document indicating which sections of such document shall be included in the request and show all such redactions, and shall consult with the other Party and other Party's counsel and provide them with a reasonable opportunity to request the inclusion of specified provisions in any request by the disclosing Party for confidential treatment.

10.4 PUBLIC ANNOUNCEMENTS. Neither Party shall make any public announcements concerning the Agreement, nor make any public statement which includes the name of the other Party or any of its Affiliates, or otherwise use the name of the other Party or any of its Affiliates in any public statement or document without the consent of the other Party, which consent shall not be unreasonably withheld, except: (a) as may be required by law or judicial order; or (b) either Party may include in a subsequent public statement or document, information regarding the Agreement which has already been approved by the other Party. A copy of the press release mutually agreed to by the Parties regarding this Agreement is attached hereto as Exhibit 10.4.

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ARTICLE 11 - TERM AND TERMINATION

11.1 TERM. Unless earlier terminated, the Term of this Agreement shall commence on the Effective Date and shall expire on December 31, 2009; PROVIDED, that one Party has provided written notice of such termination to the other Party at least six (6) months prior to such termination. During the Term, the Parties may negotiate and mutually agree to extend the Term, whether for renewal periods or for a fixed period of time.

11.2 EARLY TERMINATION . Either Party may terminate this Agreement at any time upon one hundred and eighty (180) days written notice to the other Party.

11.3 TERMINATION BASED ON CHANGE OF CONTROL EVENT. Abbott may terminate this Agreement for a Change of Control Event affecting ICU upon ninety (90) days' prior written notice to ICU.

11.4 TERMINATION FOR CAUSE. A Party may terminate this Agreement by giving the other Party sixty (60) days written notice of such termination if the other Party: (a) appoints a receiver, executes an assignment for the benefit of creditors or files or otherwise becomes subject to bankruptcy or insolvency proceedings; or (b) materially breaches or defaults in any of the material terms or conditions of this Agreement and fails to cure such breach or default within sixty (60) days of receiving notice thereof.

11.5 THE EFFECT OF TERMINATION

11.5.1 DELIVERY OF PREVIOUSLY ORDERED PRODUCTS. Upon any termination of this Agreement by ICU, Abbott shall be entitled to have delivered the Products ordered prior to termination.

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11.5.2 SURVIVAL. The following Articles or Sections shall survive the termination or earlier expiration of this Agreement: Article 1 (Definitions), Article 8 (Intellectual Property), Article 9 (Warranties, Representations and Indemnification), Article 10 (Confidentiality), Section 11.5.2 (Survival), Section 12.3 (Notices), Section 12.4 (Dispute Resolution) and Section 12.6 (Assignment).

ARTICLE 12 - MISCELLANEOUS

- 12.1 FORCE MAJEURE. Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money) shall not be considered a breach of this Agreement and the time required for performance shall be extended for a period equal to the period of such delay; provided that such delay has been caused by or is the result of any acts of God; acts of public enemy; insurrections; riots; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; or other unforeseeable causes beyond the control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible.
- 12.2 INDEPENDENT CONTRACTORS. The Parties hereto are independent contractors. Nothing contained in this Agreement shall be construed to constitute a Party as a partner, agent or joint venture with the other Party or as a participant in a joint or common undertaking with the other Party. Each Party shall be individually responsible for its own obligations and liabilities as herein provided. Neither Party shall be under the control or shall be deemed to control the other Party. Neither Party shall be the agent of or have the right or power to bind the other Party without such Party's express written consent, except as may be expressly provided in this Agreement.

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- 12.3 NOTICES. All notices hereunder shall be delivered personally; by registered or certified mail, postage prepaid; by facsimile with a confirmation copy sent by registered or certified mail, postage prepaid; or by overnight courier service, to the following addresses of the respective Parties:

If to Abbott: Abbott Laboratories
 D-960, AP30
 200 Abbott Park Road
 Abbott Park, Illinois 60064-3500
 Attention: President
 Hospital Products Division
 Facsimile No.: (847) 937-2927

With a copy to: Abbott Laboratories
 D-322, AP6D
 100 Abbott Park Road
 Abbott Park, Illinois 60064-3500
 Attention: Divisional Vice President
 Domestic Legal Operations
 Facsimile No.: (847) 938-1206

If to ICU: ICU Medical, Inc.
 951 Calle Amanecer
 San Clemente, California 92673
 Attention: Chief Financial Officer
 Facsimile No.: 949-366-8368

With a copy to: Guy Maily, Esq.
 7700 Irvine Center Drive
 Suite 800
 Irvine, CA 92718-2930
 Facsimile No.: (949) 552-2985

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Notices shall be effective upon receipt if personally delivered or delivered by facsimile, on the third Business Day following the date of mailing or on the first Business Day following deposit with an overnight courier service. A Party may change its address listed above by notice to the other Party.

12.4 DISPUTE RESOLUTION. The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. The Parties agree that any such dispute shall be resolved by Alternative Dispute Resolution (ADR). To have a dispute resolved by ADR, a Party must first send written notice of the dispute to the other Party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected divisions or business units within twenty-five (25) days after such notice is received. If the matter has not been resolved within twenty-five (25) days of the notice of dispute, or if the Parties fail to meet within such twenty-five (25) days, either Party may initiate an ADR proceeding as set forth in Exhibit 12.4 of this Agreement. The Parties shall have the right to be represented by counsel in such a proceeding.

12.5 GOVERNING LAW. This Agreement shall be construed, interpreted and governed by the laws of the State of Illinois, except for choice of law rules.

12.6 ASSIGNMENT. Neither Party shall assign this Agreement or any part thereof without the prior written consent of the other Party; provided, however: (a) either Party may assign this Agreement without consent of the other Party to a wholly-owned subsidiary of such Party; and (b) either Party may assign or sell the same without such consent in connection with the transfer or sale of substantially its entire business to which this Agreement pertains, or in the event of its merger or consolidation with another company. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any accrued obligation which such Party then has hereunder.

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12.7 SEVERABILITY. This Agreement is subject to the restrictions, limitations, terms and conditions of all applicable laws, governmental regulations, approvals and clearances. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

12.8 WAIVER. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

12.9 BINDING EFFECT. This Agreement shall be binding upon and inure to the benefits of the Parties hereto and their respective successor and permitted assigns.

12.10 INTEGRATION/MODIFICATION/ENTIRE AGREEMENT. This Agreement, together with the attached Exhibits, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supersedes all prior discussions, correspondence, negotiations, understandings or agreements. This Agreement may not be altered, amended, modified or otherwise changed in any way except by a written instrument, which specifically identifies the intended alteration, amendment, modification or other change, clearly expresses the intention to so change this Agreement, and is signed by an authorized representative of each of the Parties.

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12.11 COUNTERPARTS. This Agreement may be executed in two (2) or more counterparts, each of which when executed shall be deemed an original, and all of which together shall constitute one and the same instrument.

The Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed by their duly authorized representatives on the date below written.

ABBOTT LABORATORIES

By: /S/ CHRISTOPHER B. BEGLEY

Christopher B. Begley
President
Hospital Products Division

Date: FEBRUARY 27, 2001

ICU MEDICAL, INC.

By: /S/GEORGE A. LOPEZ, M.D.

George A. Lopez, M.D.
Chief Executive Officer

Date: FEBRUARY 27, 2001

ICU MEDICAL, INC.

By: /S/FRANCIS J. O'BRIEN

Francis J. O'Brien
Chief Financial Officer

Date: FEBRUARY 27, 2001

[Logo Here] ICU MEDICAL, INC.

ICU MEDICAL, INC. ANNOUNCES

AGREEMENT WITH ABBOTT LABORATORIES

FEBRUARY 28, 2001, SAN CLEMENTE, CALIFORNIA -- ICU Medical, Inc. (ICUI -- NASDAQ/NMS), the San Clemente based maker of safe medical connectors, today announced a new co-promotion and distribution agreement with Abbott Laboratories. As part of the eight-year agreement, ICU Medical will manufacture new custom-made intravenous (I.V.) sets for sale through Abbott's Hospital Products Division. Abbott and ICU Medical will jointly promote the products under the name SetSource(TM).

"We are excited about this opportunity to expand our relationship with Abbott," said George A. Lopez, M.D., chairman and chief executive officer, ICU Medical. "With ICU's ability to cost effectively manufacture custom sets in only days versus months for the rest of the industry, combined with Abbott's strength in the marketplace, we expect to capture significant market share in this arena."

"Plans to aggressively go after the custom I.V. market, which is estimated to be more than \$50 million, are under way," said Rich Costello, vice president, Sales, ICU Medical. "Sales are expected to start almost immediately, with a full launch scheduled within ninety days."

The foregoing statement concerning Management's expectation with respect to future results is a forward looking statement based upon the best information currently available to Management and assumptions Management believes are reasonable, but Management does not intend the statement to be a representation as to future results. Future results are subject to risks and uncertainties, including the risk factors described in the Company's filings with the Securities and Exchange Commission, which include those in the Form 8-K dated November 5, 1999. Actual results in the future may differ materially from Management's current expectations.

CONTACT: Francis J. O'Brien
Chief Financial Officer
ICU Medical, Inc.
(949) 366-2183