

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 12, 2013

UNITED-GUARDIAN, INC.

(Exact name of Registrant as Specified in Charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation)

1-10526

(Commission File Number)

11-1719724

(IRS Employer
Identification No.)

230 Marcus Boulevard, Hauppauge, New York

(Address of Principal Executive Offices)

11788

(Zip Code)

Registrant's telephone number, including area code: (631) 273-0900

Not Applicable

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement.

On November 12, 2013 the Registrant entered into a written manufacturing and supply agreement with Smiths Medical ASD, Inc. (“Smiths”), retroactive to November 1, 2013, pursuant to which Smiths would supply Registrant with a new single-dose form of one of the Registrant’s pharmaceutical products, Renacidin® Irrigation. The agreement provides for the Registrant and Smiths to work together to develop the new product and provide sufficient data for the Registrant to file a supplement to its currently approved New Drug Application for Renacidin with the U.S. Food and Drug Administration. The approval would allow the Registrant to market Renacidin in a new single dose sterile 30mL vial that would be manufactured using blow-fill-seal packaging technology. Smith’s obligations under the agreement are contingent upon the Registrant obtaining FDA approval to market the new product by March 31, 2015. The Registrant expects to file the application in the first half of 2014.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits. The following exhibits are filed with this report:

<u>Exhibit Number</u>	<u>Description</u>
10.1	Manufacturing and Supply Agreement between the Registrant and Smiths Medical ASD, Inc. signed November 12, 2013 and effective as of November 1, 2013.

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 thereunto duly authorized.

UNITED-GUARDIAN, INC.

By: /s/ Kenneth H. Globus
Name: Kenneth H. Globus
Title: President

November 14, 2013

MANUFACTURING AND SUPPLY AGREEMENT

Between

UNITED-GUARDIAN, INC.

And

SMITHS MEDICAL ASD, INC.

This MANUFACTURING AND SUPPLY AGREEMENT ("Agreement") is effective November 1, 2013 ("Effective Date"), and is made and entered into by and between **UNITED-GUARDIAN, INC.** ("UNITED"), a corporation organized and existing under the laws of the State of Delaware, USA, with its principal place of business at 230 Marcus Blvd., P.O. Box 18050, Hauppauge, NY 11788 and **SMITHS MEDICAL ASD, INC.** ("SMITHS") having offices at 600 Cordwainer Dr., 3rd Floor, Norwell, MA 02061.

WHEREAS, UNITED and SMITHS desire to enter into an Agreement for SMITHS to Manufacture the Product (as defined below) for a fee payable by UNITED to SMITHS.

WHEREAS, SMITHS has the expertise and experience necessary to Manufacture (as defined below) the Product.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the parties agree as follows:

1. DEFINITIONS

- 1.1. **"Affiliate"** means any person or entity that directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with a party, where control means the direct or indirect, legal or beneficial ownership of more than twenty percent (20%) of the outstanding voting rights in a company.
- 1.2. **"BFS"** means blow-fill-seal packaging technology.
- 1.3. **"cGMP"** means the current Good Manufacturing Practice Regulations that apply to the manufacture, processing, packing, or holding of a drug, or the Quality System Regulation that applies to the design, manufacture, packaging, labeling and storage of a finished device, as such are or may be applicable to the manufacture and packaging of the Product.
- 1.4. **"Facility"** means the facility of SMITHS located in Vernon Hills, IL used for Manufacture of the Product.
- 1.5. **"FD&C Act"** The Federal Food, Drug, and Cosmetic Act.
- 1.6. **"Manufacture"** includes all activities performed by SMITHS that are subject to cGMP, including but not limited to the process by which SMITHS utilizes its BFS and other equipment to produce and package the Product as outlined in Schedule A.
- 1.7. **"Materials"** means the specific equipment, tooling and supplies used in connection with the Manufacture of the Product, and not used in connection with the manufacture of other products by SMITHS.
- 1.8. **"Price"** means the charge to UNITED for Product supplied by SMITHS. All prices shall be in U.S. Dollars.

- 1.9. “Product”** means Renacidin® Irrigation, the pharmaceutical product listed on Schedule A attached hereto, in its final single-use dosage form.
- 1.10. “Quality Agreement”** means the agreement attached hereto as Schedule C and made a part of this Agreement.
- 1.11. “Regulatory Authority”** means any local, state, federal, or international regulatory agency, department, or bureau, including the United States Food and Drug Administration (“FDA”), which is responsible for issuing approvals, licenses, registrations, or authorizations necessary for the Manufacture, use, storage, import, transport, or sale of Product.
- 1.12. “Services”** means the operations relating to the packaging of the Product, such as quality assurance, and shipping as outlined in Schedule A.
- 1.13. “Specifications”** means the specifications contained in or referred to in the Quality Agreement, as amended from time to time.
- 1.14. “Territory”** means the United States of America.
- 1.15 “Contract Year”** means the 12-month period beginning no later than the 1st day of the first full month that begins six (6) months after UNITED receives approval from the FDA of its application to market the Product, or upon first saleable product shipments intended for United Guardian customers, whichever occurs first, and continuing for each 12-month period thereafter until this Agreement terminates. UNITED agrees to give SMITHS at least 90 days notice and lead time for all orders.

2. PACKAGE AND SUPPLY

2.1 Manufacture, Supply and Purchase Obligations. SMITHS shall Manufacture for and supply to UNITED, and UNITED shall purchase from SMITHS, such quantities of the Product as UNITED may order from SMITHS in accordance with the terms and conditions of this Agreement. Based on firm orders and forecasts provided by UNITED, and at no cost to Smiths, UNITED shall supply SMITHS with certain raw materials needed to Manufacture the Product (“Raw Materials”), which are set forth on Schedule B. Smiths shall Manufacture, test, release, and ship Product to UNITED. SMITHS shall assume all responsibility and risk, up to the replacement value, for the safekeeping, storage, and handling of all shipments of Raw Materials received from UNITED.

UNITED shall purchase all of its requirements for Product from SMITHS, and SMITHS shall sell Product exclusively to UNITED. SMITHS shall use UNITED Materials, including but not limited to UNITED molds and related equipment as set forth in Section 3.3 hereof, exclusively and solely for Manufacture of UNITED Product unless otherwise agreed.

2.2 cGMP Compliance. SMITHS shall Manufacture the Product in accordance with the Specifications, with applicable cGMP’s and with such other applicable laws and regulations as shall be set forth in the Quality Agreement.

2.3 Services and Information to be provided by UNITED.

(a) UNITED shall provide SMITHS with all necessary scientific and technical data relating to the Product, including bulk Product specifications and Product formulations subject to the confidentiality provisions set forth in paragraph 11 hereof. UNITED shall also provide all pertinent environmental health and safety information necessary to assure safe handling and disposal of the Raw Materials and the Product by SMITHS’ employees. In addition, UNITED shall, at its cost, make available to SMITHS, on an as-needed basis, the services of UNITED technicians who are familiar with such data.

(b) Without diminishing the obligation of SMITHS to comply with all applicable cGMP’s and other applicable laws and regulations, UNITED shall endeavor to notify SMITHS in writing within 30 days of any final changes to cGMP’s or other final rule or regulation of a Regulatory Authority of which UNITED becomes aware, that apply to the Manufacture of the Product.

2.4 FDA Debarment. SMITHS certifies that it is not debarred under subsection 306 (a) or (b) of the FD&C Act and that it has not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. SMITHS further certifies that it will immediately notify UNITED in writing if it becomes debarred under subsection 306 (a) or (b) of the FD&C Act.

3. LICENSE AND REGISTRATIONS

3.1 Mutual Grants. The parties acknowledge and agree that nothing herein shall be deemed to terminate the confidentiality provisions contained in the Confidentiality Agreement dated February, 21 2013, which continues to apply to all correspondence and discussions between the parties that took place prior to the effective date of this Agreement. The confidentiality provisions contained in this Agreement will control all discussions or correspondence that took place or will take place beginning on the effective date of this Agreement, and any conflict between the terms of the previous Confidentiality Agreement and the confidentiality provisions of this Agreement shall be resolved in favor of the terms herein. Nothing in this Agreement shall be construed as giving either party any license or right in trademarks, patents, designs, copyright or other intellectual property rights belonging to the other party, except that SMITHS shall have limited license to use UNITED's trademarks to the extent that SMITHS is required by UNITED to apply the same to the Product or its packaging for the purpose of this Agreement.

3.2 Regulatory Licenses. SMITHS will be responsible for, and bear the costs of, filing for all necessary permits, establishment and facility licenses required by Regulatory Authorities necessary for SMITHS to Manufacture the Product for UNITED under this Agreement. UNITED will be responsible for, and bear the costs of, filing all necessary permits, licenses, registrations, certificates, approvals and other forms of authorization from all Regulatory Authorities necessary for UNITED to market and sell the Product, including the marketing authorizations. To the extent either party possesses relevant information, SMITHS and UNITED shall cooperate in obtaining all relevant permits, licenses, registrations, certificates, approvals and other forms of authorizations. The obligation of purchase and supply as set forth in Section 2.1 shall become effective upon the granting of the necessary permits and approvals by the Regulatory Authorities.

In the event UNITED is required to file a regulatory submission due to SMITHS changing its manufacturing process, equipment, or location, and such change was not requested by UNITED, then SMITHS shall be responsible for all costs incurred by UNITED as a result of such change, including but not limited to the costs of a new mold, parison heads, or filling system, new pilot and stability batches, and the costs of preparing and submitting any new regulatory filings that are required as a result of SMITHS making such changes, including consultant costs. If a regulatory filing is required as the result of the occurrence of a Force Majeure (as defined in paragraph 15.1 of this Agreement), then UNITED agrees to pay all of the costs of such filings. In situations where the parties agree to make changes that benefit both parties, and that requires the filing of a new submission, the parties agree to share equally in the costs of that new filing.

SMITHS shall be responsible for the cost of producing any batches of Product that are required as part of any new regulatory submission pursuant to this paragraph unless either (a) the new submission is the result of a change requested by UNITED, or (b) the batches produced can be sold by UNITED. If new batches are required for a submission that benefits both parties and which was mutually agreed upon by both parties, the cost of the submission batches will be shared equally unless they can be marketed by UNITED, in which case the cost of such batches will be borne entirely by UNITED.

3.3 Ownership. The molds, associated filling systems, parison heads (if any), and any other equipment that is paid for by UNITED and used by SMITHS to Manufacture the Product (as set forth in Schedule B), shall be owned by UNITED, and for the duration of this Agreement UNITED will be solely responsible for insuring that equipment. Except as otherwise set forth herein, SMITHS shall own and have property rights to all specific Materials and general manufacturing equipment needed to Manufacture Product. Notwithstanding anything contained herein, SMITHS shall be the exclusive owner of any intellectual property rights arising from SMITHS efforts hereunder that are not specifically related to the Product, its formulation or packaging.

4. FORECASTS, ORDERS AND DELIVERY

4.1 Forecasts. On or prior to the tenth (10th) calendar day of January, April, July and October in each year during the term of this Agreement, UNITED shall provide to SMITHS a commercially reasonable rolling forecast of Product for the twelve months following the month in which such forecast is submitted. The first three (3) months of each forecast constitutes a firm order.

4.2 Orders. UNITED shall issue quarterly Purchase Orders before the tenth (10th) calendar day of each calendar quarter, specifying quantity of Product and delivery requirements for the calendar quarter following the one in which the Purchase Order was submitted.

4.3 Delivery. SMITHS shall deliver ordered quantities of the Product on or before the date specified in the applicable purchase order, provided such date is at least 90 days after receipt of the purchase order, or the alternative date agreed upon in advance with UNITED. All shipping costs are the responsibility of UNITED.

4.4 Shipments. SMITHS shall deliver with each batch of Product in a shipment a Certificate of Analysis, accompanied by a statement that the batch was Manufactured according to this Agreement (including the Quality Agreement), together with any other batch related records specified in the Quality Agreement. SMITHS shall also provide release documents at the time each batch of Product is shipped.

4.5 Obsolete Inventory. Any UNITED-specific obsolete materials purchased by SMITHS to Manufacture the Product, including but not limited to Raw Materials, work in process, and packaging materials shall be reimbursed to SMITHS by UNITED at SMITHS costs. The maximum amount of obsolete inventory that UNITED will reimburse SMITHS for will be that associated with the first three (3) months of the most current forecast. At such time as agreed by both parties UNITED shall bear the cost of shipment to UNITED or all destruction costs related to said inventory unless otherwise agreed to in writing. United's obligation is limited to Raw Materials, packaging materials and work in process labor. Any finished goods produced under a firm order shall be purchased by UNITED at the contracted price.

5. DELIVERY

5.1 Terms of Delivery. The Product shall be shipped from SMITHS to a destination designated by UNITED. Each shipment shall be Ex Works Vernon Hills, IL. The transportation costs for shipment of Product from SMITHS to UNITED designated location shall be borne by UNITED. Transportation shall be arranged by SMITHS to occur in full-truckload quantities when possible.

6. PRICES AND PAYMENT

6.1 Price. The prices for the Product shall be as set forth on Schedule B.

6.2 Payment. Payment of the Price shall be made within thirty (30) days from date of receipt of the SMITHS invoice. SMITHS shall date and send invoices to UNITED for the Product upon shipment of the Product to UNITED. If UNITED fails to pay or procure payment of the full amount of any invoice when due, and without in any manner excusing such violation, UNITED agrees to pay SMITHS interest at a rate of 1.5% per month (or the highest rate permitted by applicable laws, if lower) on the amount due and owing to SMITHS, from the date the payment is due until paid. Without prejudice to any of its other rights, SMITHS may withhold shipments of the Product if UNITED has not paid an invoice when due.

6.3 Adjustment of Price. Prices do not include, and UNITED is responsible for, any and all applicable taxes and governmental fees, assessments, duties and charges. The prices for the Product for the first three (3) years following the Effective Date of this Agreement are provided in Schedule A. Thereafter, Smiths may increase once per year, provided that UNITED is notified in writing sixty (60) days in advance of each subsequent adjustment. For any price increase in excess of 5% in any one year, within thirty (30) days after the receipt of notice of the price increase, UNITED may request written documentation from SMITHS showing the increase in the amount of Smiths' costs for labor or components used in manufacturing the Product that is the basis for such price increase, and SMITHS shall furnish such documentation within thirty (30) days thereafter, and any such price increase in excess of 5% will be limited to the documented labor and component cost increases. Any such adjustment to price shall be evidenced as an amendment to Schedule A

of this Agreement and signed by both parties. Notwithstanding the foregoing, if unforeseen market issues arise during the term of the Agreement that require further consideration relative to price adjustments, the parties will promptly and fairly address this issue.

7. WARRANTY

7.1. SMITHS' Warranty. SMITHS warrants to UNITED that the Product, at the time of delivery to UNITED as provided in Section 5: (i) will conform to the Specifications as then in effect, (ii) were Manufactured in accordance with cGMP and other applicable legal requirements relating to the manufacturing of Product, and (iii) are free and clear of all liens or encumbrances; (iv) are not adulterated as defined under Title 21 - FOOD AND DRUGS: CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT: SUBCHAPTER V - DRUGS AND DEVICES: Part A - Drugs and Devices: Sec. 351 - Adulterated drugs and devices. However, SMITHS shall not be responsible in the event adulteration was caused by adulterated Raw Materials provided by United. SMITHS further warrants to UNITED that through the expiration date, Product: (I) will be free from any defects in material and workmanship, and (II) will not fail to meet Specifications for a reason that is attributable to any deviations by SMITHS from cGMP. SMITHS acknowledges that the properties of the plastic bottle are such that they may be subject to change based upon heat, cold and method of packaging, freight and handling. Due to the uncertainty of these variables, SMITHS agrees to use commercially reasonable efforts in preparing Product for shipment. To the extent that a claim is made that Product fails to comply with the Specifications and such claim is related solely to a deformity or defect in the Product that may be environmentally related, it shall be UNITED's obligation to show that the carrier stored and transported Product in accordance with the environmental parameters. SMITHS' sole obligation and Buyer's exclusive remedy for any breach of the warranty in this Section 7.1 will be replacement of the defective Product.

7.2 Mutual Representations. Each party hereby represents and warrants that it has the full power and authority to enter into and perform this Agreement, and each party knows of no contract, agreement, promise, undertaking or other fact or circumstance that would prevent the full execution and performance of this Agreement.

8. QUALITY CONTROL REQUIREMENTS

8.1 General. SMITHS shall perform quality control release testing of the Product, in accordance with cGMP and all other applicable regulatory requirements and agreed analytical and other testing procedures for Product release. UNITED shall at its own expense conduct inspections and tests as it deems necessary to determine the acceptability of the Product for distribution into interstate commerce within 30 days after receipt of delivery. Should UNITED fail to inspect the Product within that time or fail to notify SMITHS of any deficiency within 30 days UNITED shall be deemed to have inspected and approved the Product. Notwithstanding anything herein to the contrary, the thirty (30)-day notice provision shall not apply to any latent defect that is not, or could not, be detected within that timeframe by standard accepted QC inspection protocols.

8.2 Stability and Sterility Assurance. SMITHS shall perform any sterility testing of the Product in accordance with cGMP and all other applicable regulatory requirements, such testing costs to be borne by SMITHS. UNITED will be responsible for the cost of all analytical and stability and agreed analytical and testing procedures with costs borne by UNITED.

8.3 Quality Agreement. The Product shall be Manufactured in accordance with the Quality Agreement. The parties shall agree upon reasonable tests to be undertaken by SMITHS prior to release and shipment of the Product, including all inspection methods to determine the acceptability of a batch, and such procedures shall be a part of or appended to the Quality Agreement (Schedule C) and incorporated therein. This section is subject to Section 8.1.

8.4 Inspections.

(a) UNITED shall subject a Product to a quality control inspection in accordance with the applicable UNITED quality control standards and procedures at UNITED's discretion as set forth in the Quality Agreement.

(b) At a reasonable time but no more than once per year (or such additional times as mandated by a Regulatory Authority or as necessary for investigation of an issue related to Quality Controls), upon at least 48 hours notice, SMITHS shall permit UNITED, or its representatives, to inspect during regular business hours SMITHS' manufacturing facility for the purpose of assuring compliance with cGMP and any other applicable regulatory and quality assurance requirements, procedures or standards. Upon reasonable prior notice, SMITHS shall permit UNITED to review periodically SMITHS' quality control procedures and records, at reasonable times with a representative of SMITHS present, in order to assure satisfaction of the requirements of this Agreement. The use of any third party representative shall be subject to SMITHS' reasonable consent. Any such representative shall be required as a condition to an inspection to execute SMITHS' non-disclosure agreement and to abide by such other conditions as SMITHS reasonably deems necessary for the protection of its confidential or proprietary information. UNITED shall be responsible for any breach of confidentiality by any such representative.

(c) SMITHS shall (i) fully cooperate with UNITED or its representatives who may visit SMITHS' production facility as provided in Section 8.4(b), (ii) take appropriate corrective action within 15 days or another reasonable number of days as agreed to by the parties (or immediately if there are issues of safety, health, etc.) of notification to comply with cGMP requirements, and (iii) when requested by UNITED, describe in writing corrective action planned or taken.

8.5 Regulatory Inspections. In the event that any portion of the SMITHS facility involved in the Manufacture of Product or any aspect of its Quality Control System that is relevant to SMITHS's Manufacture of the Product is the subject of an inspection by any Regulatory Authority or any other duly authorized agency of any national, state, or local government, SMITHS shall notify UNITED promptly upon learning of such inspection and shall supply UNITED with copies of any correspondence or portions of correspondence that relate to the Product. In the event that either party receives any correspondence or other communication from any Regulatory Agency relating to the Manufacture of the Product, it shall provide the other party with a copy of each such communication and the proposed response.

8.6 Records. UNITED shall have the right to audit SMITHS's records relating to its performance under this Agreement. SMITHS shall maintain reserve samples, all batch and other packaging and analytical records, all records of shipments of Product and all validation data relating to the Product, and other applicable records, for the time periods required by applicable laws and regulations, and shall make such data available to UNITED and Regulatory Authorities upon UNITED's reasonable request or if required by law.

9. REJECTION

9.1 General. In the event that any portion of the Product delivered to UNITED by SMITHS shall fail to conform to any of the Specifications, UNITED may reject that portion by giving written notice to SMITHS within 30 days after receipt of delivery. SMITHS shall be given an opportunity to investigate whether or not the Product meets Specifications and if it is agreed that the Products do not meet specifications, UNITED shall be entitled to return such non-conforming Products to SMITHS at SMITHS' expense, and to receive fully compliant Product in replacement, subject to SMITHS having in stock relevant materials and components.. If there is a disagreement as to whether product is conforming or not, the product will be sent to an independent laboratory for a final determination, the cost of which shall be borne by the party whose determination of conformance or non-conformance was incorrect. If it is determined that the product is non-conforming, UNITED shall destroy any non-conforming Product at SMITHS's expense, and in accordance with all applicable legal requirements. This section is subject to Section 8.1. SMITHS shall reimburse UNITED for the cost of all Raw Materials lost as a result of Product failing to meet Product specifications.

9.2 Dispute Resolution. If SMITHS disputes UNITED's rejection, the parties shall submit samples of the rejected Product for analysis to a mutually acceptable independent laboratory, whose decision in the matter shall be final and binding. The costs of such analysis shall be borne by SMITHS, unless such analysis shows that the Product met the Specifications, in which case UNITED shall bear the cost of such analysis.

10. INDEMNIFICATION

10.1 SMITHS. Except to the extent that UNITED is required to indemnify SMITHS under Section 10.1 of this Agreement, SMITHS shall defend and hold UNITED and its Affiliates, as well as its shareholders, directors, officers, employees and agents harmless from any and all liability, costs, claims and expenses, including reasonable attorney's fees, arising from third party claims for death or injury to person or damage to tangible property as a consequence of a defective Product manufactured and supplied by SMITHS under this Agreement, unless the defect is caused by the Raw Materials provided by UNITED to SMITHS.

SMITHS SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUSTAINED OR INCURRED BY UNITED IN CONNECTION WITH THE PRODUCT SUPPLIED HEREUNDER. THE WARRANTIES SET OUT IN THIS AGREEMENT ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANT ABILITY AND FITNESS FOR A PARTICULAR PURPOSE. SMITHS DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES.

10.2 UNITED shall defend, indemnify and hold SMITHS and its Affiliates, their shareholders, directors, officers, employees and agents harmless from and against any and all liability, loss, damage, causes of action, suits, claims, demands, settlements, costs and expenses or judgments of any nature whatsoever, resulting from the Product or their marketing, sale, clinical testing, clinical use or other use (or misuse), including any design defect, failure to warn or other product liability or intellectual property claims, except to the extent SMITHS is required to indemnify UNITED under Section 10.1 of this Agreement.

10.3 Defense Control. To the extent a party shall be required to indemnify the other party; such indemnifying party shall have control of the defense and settlement thereof, but no party shall settle a claim that admits fault on the part of the other party without such party's written consent, not to be unreasonably withheld or delayed. The obligation to indemnify shall be applicable so long as the indemnified party gives prompt notice of the claim to the indemnifying party and provides the indemnifying party with such assistance as is reasonably required under the facts and circumstances.

11. CONFIDENTIALITY

11.1 General. Each party shall hold in strictest confidence all information supplied by the other party ("Discloser"), including but not limited to all written material, product samples, Specifications, drawings, designs, plans, layouts, forecasts, product formulations, business plans and financial information, procedures, computer programs, models, prototypes or other information of any description ("Confidential Information") received from the other party (the "Discloser") for a period of seven (7) years after the date of disclosure. During the period of confidentiality, the receiving party ("Recipient") agrees not to divulge any of the Confidential Information to any third party (except to employees and legal or financial advisors on a need-to-know basis, all of whom shall be required by Recipient to be bound by the same degree of confidentiality as Recipient), nor to use the Confidential Information for any purpose other than as agreed by the disclosing party.

11.2 Confidential Information may be disclosed either orally or in writing, including graphic material and electronic, magnetic or other data, may be disclosed either orally or in writing to an employee of the Recipient on a need to know basis only. When disclosed in writing, the information will be labeled as confidential by the Discloser. When disclosed orally, such information will be identified as confidential at the time of disclosure, with subsequent confirmation in writing referencing the type of information disclosed. Regardless of whether such information is labeled or confirmed in writing, any such information that would be known to a reasonable person under the circumstances shall be deemed Confidential Information. Confidential Information shall not be deemed to include:

- (a) information which is or becomes generally available to the public otherwise than through a breach of this Agreement;
- (b) information which Recipient can establish, by its written records, was in its possession prior to the disclosure hereunder, or was developed independently of any disclosure hereunder; or

(c) information which is approved in writing by the Discloser for release by Recipient.

11.3 It is understood and agreed that the disclosure of Confidential Information by the Discloser shall not grant Recipient any express, implied or other license or rights to patents or trade secrets of the Discloser (including any subsidiary or Affiliate thereof), nor shall it constitute any sort of joint venture or undertaking between the parties.

11.4 Recipient shall secure documents, information, items of work-in-process and work products that embody Confidential Information in the same manner that it secures its own confidential information of like sensitivity. In addition, Recipient shall maintain reasonable procedures to prevent loss of any confidential or proprietary documents. In the event of any loss, the Discloser shall be promptly notified of such loss.

11.5 Recipient agrees to return all Confidential Information, including all copies thereof upon written demand by the Discloser.

11.6 All materials, drawings, designs, specifications, notes, memoranda, or data furnished shall be and remain the property of the Discloser.

11.7 Recipient shall not be in breach of this Agreement if it discloses Confidential Information pursuant to a demand by a court or judicial or governmental authority of proper jurisdiction (including the FDA) with which Recipient is obliged to comply, provided Recipient will provide Discloser with reasonable notice of such demand and take such steps as Discloser may reasonably request to assist Recipient in obtaining a protective order preventing or limiting the disclosure and/or any other measures requiring that the Confidential Information be protected.

12. TERM AND TERMINATION

12.1 Term. This Agreement shall be binding on both parties as of the Effective Date specified above and, unless terminated in accordance with Section 12.2 or 12.3 below, shall remain in full force and effect for 6 years from the date UNITED receives FDA approval of its application to market the Product ("Term"). The Term may only be extended by mutual written agreement of the parties.

12.2 Automatic Termination. Unless UNITED has not received FDA approval of its application to market the Product and provided notice to this effect to SMITHS by the end of the business day on March 31, 2015, this Agreement will automatically terminate at the end of the business day on March 31, 2015.

12.3 Early Termination. Without prejudice to any other rights that it may have hereunder or by law or in equity, either party may terminate this Agreement immediately by written notice to the other party upon the occurrence of any of the following:

- (a) the other party becomes insolvent or an order for relief is entered against the other party under any bankruptcy or insolvency laws or laws of similar import;
- (b) the other party makes an assignment for the benefit of its creditors or a receiver or custodian is appointed for it or its business is placed under attachment, garnishment or other process involving a significant portion of its business; or
- (c) the other party is guilty of a material breach of its undertakings or warranties under this Agreement and, after thirty (30) days written notice from the terminating party specifying the breach and stating its intent to so terminate, fails to cure the breach.

In addition to the termination rights above, UNITED shall have the right to terminate this agreement within 10 days after its initial visit to SMITHS manufacturing facility (but no later than March 1, 2015 if no visit takes place before that date), should Smiths' Vernon Hills manufacturing site have any negative changes to its accreditation, its manufacturing facility, its ability to manufacture Product in accordance with cGMPs, or if any Form 483s are issued by the FDA and go unresolved as per required FDA guidelines.

12.4 Effect of Termination. Termination of this Agreement shall not release either Party from fulfilling any obligations it may have incurred prior to such termination. Notwithstanding such termination or expiration, the provisions set forth in the Sections 3.3, 7.1, 7.2, 8.1, 8.5, 10, and 11 shall survive termination of the Agreement. Upon the expiration or termination of this Agreement, SMITHS shall reasonably cooperate with UNITED in the transfer of production of the Product to such production facility designated by UNITED whereby UNITED shall bear cost and expense of transferring said Product and equipment and, subject to UNITED's reimbursement of all costs reasonably incurred by SMITHS, provide reasonable technical and regulatory assistance, with a view to the continued supply to UNITED of Product as contemplated by this Agreement. Notwithstanding anything herein, termination shall not relieve UNITED of its obligations to pay for Product ordered prior to the termination notice nor shall either Party be relieved by virtue of a notice of termination of any of their obligations that by their nature survive termination of this Agreement.

13. RECALL

13.1 Product Recall. In the event (i) any national government authority or other regulatory agency issues a request, directive or order that the Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) UNITED reasonably determines after consultation with SMITHS that the Product should be recalled because the Product does not conform to the specifications at the time of shipment by SMITHS, or (iv) UNITED reasonably determines that the Product should be recalled for any reason, the parties shall take the appropriate actions to effect the recall. UNITED shall be responsible for bearing all costs associated with a recall unless such recall results primarily from the breach of SMITHS's express warranty under Article 7.1 of this Agreement in which case SMITHS shall be responsible for all the reasonable expenses of recalling the Product (including, but not limited to notification and shipping charges and man-hours spent arranging, coordinating and conducting the recall).

13.2 Recall Administration and Product Returns. UNITED will be responsible for all returns and all aspects of any recall except as provided in Article 13.1 above. Procedures for handling returns will be covered by communications from UNITED to SMITHS. UNITED will reimburse SMITHS for any and all reasonable expenses incurred by SMITHS in processing and/or disposing of any returns unless such returns are deemed to be the responsibility of SMITHS in accordance with article 13.1 above.

14. ADVERSE REACTION RESPONSIBILITY

14.1 General. Except where SMITHS is obligated by law to author a notification, UNITED will be solely responsible for processing and providing all legally required notification to the proper authorities for all adverse reaction and/or complaint calls and or correspondence related to the Product. UNITED will notify SMITHS in writing of all adverse reactions and/or complaints related to alleged defects with the Manufacturing of the Product. SMITHS shall have the right to participate in and direct all responses related to the packaging and quality of Product Manufactured by SMITHS. SMITHS agrees to report per its standard operating procedures by phone and in writing material adverse complaints including complaints of adverse reactions to the Product or in relation to SMITHS's Manufacturing of the Product, regardless of what is being alleged.

15. GENERAL PROVISIONS

15.1 Force Majeure. Neither party hereto shall be responsible or liable in any way for failure or delay in carrying out the terms of this Agreement (other than the obligation to make payment for Products delivered) resulting from any cause or circumstance beyond its reasonable control, including, but not limited to, fire, flood, other natural disasters, war, terrorism, interruption of transit, accident, explosion, civil commotion, inability of SMITHS to obtain raw materials or packaging materials (in the event this occurs, the parties will mutually agree to work together to resolve the situation as quickly as possible), and acts of any governmental authority; provided, that the party so affected shall give prompt notice thereof to the other. No such failure or delay shall terminate this Agreement, and each party shall complete its obligations hereunder as promptly as reasonably practicable following cessation of the cause or circumstances of such failure or delay; provided however, that if any of the above conditions continues to exist for more than 90 days after the date of notice given with regard thereto, either party may terminate this Agreement forthwith upon notice to the other.

15.2 No Agency. Neither party is, nor will it be deemed to be, an agent or legal representative of the other party for any purpose. Neither party will be entitled to enter into any contracts in the name of, or on behalf of the other party, nor will a party be entitled to pledge the credit of the other party in any way or hold itself out as having authority to do so.

15.3 Choice of Law and Jurisdiction. This Agreement, along with the schedules attached, incorporated and referenced herein and all purchase orders issued hereunder shall be governed and interpreted, and all rights and obligations of the parties shall be determined, in accordance with the laws of the State of New York, without regard to its conflict of laws rules. Any dispute, controversy or claim under this Agreement shall be brought in a court of competent subject matter jurisdiction in New York, and both parties agree to accept the personal jurisdiction of such court. Both Parties knowingly and willingly waive their respective right to a trial by jury in any action or proceeding related to this Agreement.

15.4 Notices. All notices, requests, demands, waivers, consents, approvals or other communications to any party hereunder shall be in writing and shall be deemed to have been duly given if delivered personally to such party or sent to such party by facsimile transmission or by registered or certified mail, postage prepaid, to the addresses set forth below (or to such other address as the addressee may have specified in notice duly given to the sender as provided herein):

If to SMITHS:

SMITHS Medical
330 Corporate Woods Parkway
Vernon Hills, IL 60061
Attn: Robert Turoff, Director of Operations
Facsimile: 847-793-0320

With copy to:

SMITHS Medical
Office of General Counsel
1265 Grey Fox Road
St. Paul, MN 55112

If to UNITED:

Ken Globus
General Counsel
230 Marcus Blvd.
Hauppauge, NY 11788

Such notice, request, demand, waiver, consent, approval or other communications will be deemed to have been given as of the date so delivered, sent by facsimile transmission, or five (5) days after so mailed.

15.5 Severability. In the event that any provision of this Agreement shall be found in any jurisdiction to be in violation of public policy or illegal or unenforceable in law or equity, such finding shall in no event invalidate any other provision of this Agreement in that jurisdiction, and this Agreement shall be deemed amended to the minimum extent required to comply with the law of such jurisdiction.

15.6 Entire Agreement. This Agreement, along with any schedules attached, incorporated and referenced herein, states the entire agreement reached between the parties hereto with respect to the transactions contemplated hereby and may not be amended or modified except by written instrument mutually agreed and signed by the parties and attached hereto. To the extent of any conflict therein, the terms of the Quality Agreement shall take precedence over all other terms, provisions, documents, schedules, or exhibits of this Agreement, while the terms of Schedule B shall take precedence over all other terms, provisions, documents, schedules or exhibits of this Agreement with the exception of the Quality Agreement.

15.7. No Waiver. The failure of either party hereto to enforce at any time, or for any period of time, any provision of this Agreement shall not be construed as a waiver of such provision or of the right of such party thereafter to enforce each and every provision. Any waiver by a party of any of its rights under this Agreement shall be in writing signed by such party.

15.8 Assignment, Binding Effect. Neither party shall assign this Agreement nor any of its respective rights or obligations hereunder without the prior written consent of the other party, which consent will not be unreasonably withheld, conditioned or delayed except to any Affiliate in which event no consent from the other party is required or as otherwise permitted hereunder. UNITED may, however, assign this Agreement to any third party that acquires UNITED's rights in the Product, provided the assignee shall have the resources to comply with all of UNITED's obligations and shall agree in writing to be bound by the terms of this Agreement. Either party may assign this Agreement in connection with a sale of all or substantially all of its assets. SMITHS will assign this Agreement to any third party that acquires SMITHS. In the event of an acquisition of SMITHS by any third party or discontinuation of SMITHS's manufacturing operations at its Vernon Hills location, UNITED may move or take possession of any equipment at any SMITHS location that it owns or has purchased, directly or indirectly, pursuant to SMITHS completing the terms of this Agreement. Any attempted assignment except as provided herein shall be void and ineffective. This Agreement and the rights herein granted shall be binding upon and shall inure to the benefit of UNITED and SMITHS and their respective successors and permitted assigns.

15.9 Headings. All section headings contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.

15.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall be deemed to be an original, and all of which taken together shall constitute one and the same instrument.

15.11 Amendments. No modification, alteration or amendment of this Agreement shall be binding upon the parties unless contained in a writing signed by a duly authorized agent for each respective party and specifically referring hereto.

15.12 Judicial Proceeding. If any judicial proceeding is necessary to enforce or interpret the terms of this agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and expenses in addition to any other relief to which such party is entitled.

IN WITNESS WHEREOF, this Agreement has been duly executed and delivered as of the day and year first above written.

UNITED-GUARDIAN, INC.

SMITHS MEDICAL ASD, INC.

BY: _____

BY: _____

NAME: Ken Globus

NAME:

TITLE: President

TITLE:

DATE: _____

DATE: _____