

# REGENICIN, INC.

## FORM 8-K/A (Amended Current report filing)

Filed 10/12/10 for the Period Ending 08/13/10

Address	10 HIGH COURT LITTLE FALLS, NJ 07424
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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K/A

CURRENT REPORT

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

Date of Report (Date of earliest event reported): August 13, 2010

**REGENICIN, INC.**

(Exact name of registrant as specified in its charter)

Nevada  
(State or other jurisdiction of incorporation)

333-146834  
(Commission File Number)

27-3083341  
(I.R.S. Employer Identification No.)

10 High Court, Little Falls, NJ 07424  
Address of principal executive offices

Registrant's telephone number, including area code: (973) 557-8914

\_\_\_\_\_  
(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 (17CFR 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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### **Explanatory Note**

The registrant files this Amendment No. 2 to the Form 8-K filed on August 18, 2010 to include Exhibit 10.4 under a request for confidential treatment with the Securities and Exchange Commission.

## **SECTION 1 – Registrant’s Business and Operations**

### **Item 1.01 Entry into a Material Definitive Agreement**

#### ***Securities Purchase Agreement***

On August 16, 2010, we sold 4,035,524 shares of our common stock as part of a Securities Purchase Agreement with certain accredited investors (the “Purchasers”) pursuant to the closing of our Private Placement Offering (the “Offering”). We received aggregate gross proceeds from the Purchasers of \$2,502,025 from the sale of the common stock.

The Purchasers are entitled to certain contractual benefits under the Securities Purchase Agreement, which are summarized as follows:

- For as long as any Purchaser holds our securities, the right to participate in any subsequent financing of our company;
- For as long as any Purchaser holds our securities, restrictions on our ability to issue securities that are convertible into common stock at some future or variable price; and
- For twelve months, restrictions on our ability to undertake a reverse or forward stock split of our common stock.

Further under the Securities Purchase Agreement, we are permitted to issue common shares that are exempt from the above restrictions in certain instances, including limited issuances to employees, officers or directors of the Company pursuant to any stock or option plan.

Pursuant to a Registration Rights Agreement that accompanies the Securities Purchase Agreement, we agreed to file an initial registration statement covering the resale of the common stock no later than 45 days from the closing of the Offering and to have such registration statement declared effective no later than 180 days from filing of the registration statement. The Offering has closed. If we do not timely file the registration statement, cause it to be declared effective by the required date, or maintain the filing, then each Purchaser in the offering will be entitled to liquidated damages equal to 1% of the aggregate purchase price paid by such Purchaser for the securities, and an additional 1% for each month that we do not file the registration statement, cause it to be declared effective, or fail to maintain the filing.

The foregoing is not a complete summary of the terms of the offering described in this Item 1.01, and reference is made to the complete text of the Securities Purchase Agreement and the Registration Rights Agreement attached hereto as Exhibits 10.1 and 10.2.

#### ***Lonza Agreement***

Under the Know How License and Stock Purchase Agreement (the “Lonza Agreement”) that we signed with Lonza Walkersville, Inc. (“Lonza”), upon the payment of \$3 million to Lonza we will receive an exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration (“FDA”) for the commercial sale of PermaDerm™, and Lonza will provide us with certain related assistance and support. We have previously paid Lonza a total of \$700,000 toward this Agreement. Following the Initial Closing of the above stock sale, we directed our escrow agent to disperse the remaining \$2,300,000 to Lonza to fulfill our obligations under the Lonza Agreement.

PermaDerm™ is the only tissue-engineered skin prepared from autologous (patient's own) skin cells. It is a combination of cultured epithelium with a collagen-fibroblast implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier, and in clinical studies to promote closure and healing of burns. Critically, self-to-self skin grafts for permanent skin tissue is not rejected by the immune system of the patient, unlike with porcine or cadaver grafts in which rejection is an important possibility.

We believe we can create and implement a successful strategy to conduct additional human clinical trials and to assemble and present other relevant information and data in order to obtain the necessary approvals for PermaDerm™ and possible related products.

#### ***Lock-up Agreements and Reserve for Equity Incentive Plan***

At the close of the Offering, all officers, directors and key employees of our company, as well as any 5% holders of our securities, entered into lock-up agreements with us for a term of 12 months whereby they agreed to certain restrictions on the sale or disposition of all the common shares held by them.

Our CEO, Randall McCoy further agreed to restrict the sale of 11,288,850 shares of his common stock representing 20% of the number of shares of common stock beneficially owned by him, until such time as we receive approval from the FDA for the commercial sale of PermaDerm™.

Mr. McCoy also agreed to cancel and return to our treasury 4,428,360 shares of his common stock to off-set the potential dilution caused by an equity incentive plan for directors involving the same number of shares that we intend to adopt in the near future.

### **SECTION 3 – Securities and Trading Markets**

#### **Item 3.02 Unregistered Sales of Equity Securities**

The information set forth in Item 1.01 of this Current Report on Form 8-K that relates to the unregistered sales of equity securities is incorporated by reference into this Item 3.02.

Aside from the \$2,502,025 that was raised in the Offering described in Item 1.01, we converted our senior secured convertible promissory notes (the "Bridge Notes") in the aggregate principal amount of \$750,000 that were previously issued to ten accredited investors into common stock. The Bridge Notes provided for a conversion rate of one share per \$0.465 of principal and interest. These conversion terms effectively represent a 25% discount to the purchase price per share in the Offering. As such, we issued 1,612,903 shares of our common stock to the note holders.

We previously announced that the placement agents in the Offering agreed to exchange their Offering fee of 7% of the aggregate amount raised into an Offering Subscription at the price per share equal to the other Purchasers in the Offering. Instead, however, the placement agents are now to receive their Offering fee in the amount of 7% the aggregate amount raised in the Offering out of the proceeds.

The common stock was offered solely to “accredited investors” in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933, as amended, and/or Rule 506 of Regulation D promulgated thereunder.

## **Section 9 – Financial Statements and Exhibits**

### **Item 9.01 Financial Statements and Exhibits**

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
<b><u>No.</u></b>	
10.1	Form of Securities Purchase Agreement*
10.2	Form of Registration Rights Agreement*
10.3	Form of Lock-Up Agreement*
10.4	<a href="#">Know-How and Stock Purchase Agreement**</a>
10.5	Agreement*

\*previously filed

\*\* Filed with the Securities and Exchange Commission under a request for confidential treatment.

## **SIGNATURES**

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

**REGENICIN, INC.**

/s/ Randall McCoy  
Randall McCoy  
CEO and Director  
Date: October 11, 2010

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**KNOW-HOW LICENSE AND STOCK PURCHASE AGREEMENT**

**THIS AGREEMENT** is made and entered into as of the day it has been signed by both parties below

**by and between:**

**Regenicin, Inc.**, having a principal address at 10 High Court, Little Falls, NJ 07424 (hereafter Regenicin); and **Lonza Walkersville, Inc.**, having a principal address at 8830 Biggs Ford Road, Walkersville, MD 21793 (hereafter LWI or Lonza);

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Exhibit A - List of Patent Rights \*

Exhibit B - Hourly rate for calculation of cost of Future Know-How \*

Exhibit C - AFIRM Grant Application \*

Exhibit D - The Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation. \*

Exhibit E - The First Amendment to the Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation. \*

Exhibit F - The License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand. \*

Exhibit G - Amendment to the License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand .\*

Exhibit H - Settlement Agreement and Release dated February 2, 2006 between the Shriners Hospital for Children, Cutanogen Corporation, the Shareholders of Cutanogen Corporation, and Cambrex Bio Science Walkersville, Inc. \*

Exhibit I - Manufacturing Agreement.

Exhibit J - Stock Purchase Agreement.

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

**WHEREAS**, LWI owns all of the issued and outstanding capital stock of Cutanogen Corporation;

**WHEREAS**, LWI is engaged in the research and development of products used in the life sciences industry, including engineered skin substitute called PermaDerm™;

**WHEREAS**, Regenicin wishes to assume responsibility for developing PermaDerm™, and to purchase the outstanding capital stock of Cutanogen Corporation;

**NOW, THEREFORE**, in consideration of the promises and of the mutual covenants and agreements herein set forth, the parties hereto agree as follows:

**Article 1. Definitions**

1.1 "Affiliate" means any corporation, company or other entity which directly or indirectly controls, is controlled by, or is under common control with, L WI or Regenicin. For the purpose of this definition, the word "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting stock of the corporation, company, or other entity.

1.2 "Contract Product" means the autologous engineered skin supplement known as PermaDerm™.

1.3 "Current Know-How" means Know-How that is in the possession of LWI, and that exists on the effective date of this Agreement.

1.4 "Future Know-How" means Know-How that is developed after the effective date of this Agreement by L WI at the reasonable request of Regenicin.

1.5 "Know-How" means information in support of a clinical trial for the Contract Product, including, without limitation, information relating to product specifications, manufacturing, testing, facilities, etc. Know-How includes, but is not limited to, Master Batch Records and SOP's.

1.6 "Patent Rights" shall mean all patents and patent applications in any country or region of the world that cover Contract Product, and that are owned by or are licensed to, L WI including, without limitation, the patents and patent applications that were licensed by LWI from the University of California, and from the University of Cincinnati and the Shriners Hospital for Children. A partial list of Patent Rights is set forth in Exhibit A.

## **Article 2. Obligations of the Parties**

2.1 This Agreement shall only become effective upon Lonza's receipt of payment in full to be made by Regenicin of the amount due under paragraph 6.1 below (the "Effective Date").

2.2 During the term of this Agreement, the obligations of LWI shall include, without limitation:

- a. produce and transfer Future Know-How to Regenicin in accordance with paragraph 3.2 below;
- b. monitor prosecution and maintenance of Patent Rights in accordance with paragraph 5.2 below;
- c. maintain the Licenses, as defined below; and
- d. execute the Stock Purchase Agreement in accordance with Article 9.1 below.

2.3 During the term of this Agreement, the obligations of Regenicin shall include, without limitation:

- a. reimburse LWI for transferring Current Know-How in accordance with paragraph 6.1 below
- b. conduct pre-clinical and clinical trials in accordance with paragraph 8.1 below;
- c. apply for and obtain approval from the FDA for commercial sales of Licensed Product in accordance with paragraph 8.1 below;
- d. reimburse LWI for providing Future Know-How in accordance with paragraph 3.3 below;
- e. reimburse L WI for monitoring prosecution of Patent Rights in accordance with paragraph 5.6 below;
- f. reimburse L WI for maintaining the Licenses in according with paragraph 5.7 below; and
- g. execute the Stock Purchase Agreement in accordance with Article 9.1 below.
- h. Pay the purchase price for the outstanding capital stock of Cutanogen Corporation in according with paragraph 6.2 below.

### **Article 3. Know-How**

3.1 Regenicin acknowledges LWI has transferred the Current Know-How.

3.2 Upon the reasonable request of Regenicin, LWI shall produce and transfer to Regenicin Future Know-How.

3.3 LWI shall send invoices to Regenicin for expenses related to the production and transfer to Regenicin of Future Know-How at a rate based on the number of hours spent by employees of LWI in accordance with the rate provided in Exhibit B, which may be updated from time to time by Lonza.

### **Article 4. Grant**

4.1 LWI grants to Regenicin, and Regenicin accepts, an exclusive license to use Know-How for the sole purposes of seeking FDA approval and, upon such approval, to use, market, offer for sale, sell and otherwise dispose of the Contract Product on a worldwide basis, subject to the terms of this Agreement. Notwithstanding the foregoing, to the extent that any grant of rights to Regenicin hereunder would constitute a transfer, assignment or sublicense of Lonza's or Cutanogen Corporation's right, interest or title in intellectual property that would trigger any milestone payments under the Stock Purchase Agreement, dated December 2005, by and among Lonza, Cutanogen Corporation and the shareholders of Cutanogen Corporation, then such portion of such grant shall be of no force and effect.

4.2 No licenses or rights, including, without limitation, sublicenses under the Licenses, other than those explicitly granted hereunder are, or shall be deemed to have been, granted under this agreement.

4.3 LWI applied for a grant from the Armed Forces Institute of Regenerative Medicine relating to the Contract Product on March 3, 2009 (hereafter AFIRM Grant Application, attached hereto as Exhibit C). Any money received by Lonza during the term of this agreement as a result of the AFIRM Grant Application shall be applied by LWI to development of the Contract Product in compliance with the conditions of the grant, and the results thereof transferred to Regenicin to the extent permitted under the grant.

4.4 LWI applied for a grant from \* relating to the Contract Product (hereafter \*). Any money received by Lonza during the term of this agreement as a result of the \* or any other grant relating to the Contract Product shall be applied by LWI to development of the Contract Product in compliance with the conditions of such grant, and the results thereof transferred to Regenicin to the extent permitted under such grant.

4.5 With respect to the AFIRM grant and any other grant that Lonza or its affiliates receives relating to the Contract Product, including, but not limited to, any grant from \*, Lonza or its affiliate(s), as the case may be, shall control all such grants and shall be the only point of contact or interface with the grantor. Regenicin shall not be permitted to communicate, directly or indirectly, with the grantor without the express written permission of Lonza.

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

## **Article 5. Patent Rights**

5.1 The parties acknowledge that certain Patent Rights relating to the Contract Product were licensed to LWI in the following agreements (hereafter, collectively, the Licenses): Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation for "Living Human Skin Replacements and Cultured Skin Substitutes" effective March 3, 2001 (hereafter California Agreement, attached hereto as Exhibit D; First Amendment to the Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation effective November 23, 2005 (hereafter California Amendment, attached hereto as Exhibit E; License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand, effective as of August 24, 1998 (hereafter Cincinnati/SHC agreement), attached hereto as Exhibit F; and Amendment to License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand, effective as of December 29, 2005 (hereafter Cincinnati/SHC amendment), attached hereto as Exhibit G.

5.2 LWI shall continue to monitor the prosecution and maintenance of Patent Rights that were licensed to LWI under the Licenses, and shall use its reasonable best efforts to obtain effective patent protection for the Contract Product under Patent Rights licensed thereunder.

5.3 Upon execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below, the California Agreement and the California Amendment will be assigned to Regenicin, subject to the written consent of the University of California in accordance with paragraph 22 of the California Agreement.

5.4 Upon execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below, the Cincinnati/SHC Agreement and the Cincinnati/SHC Amendment will be assigned to Regenicin, subject to the prior consent of the University of Cincinnati and Shriners Hospitals for Children in accordance with paragraph 14.4 of the Cincinnati/SHC Agreement.

5.5 Following the execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below, LWI will use reasonable efforts to obtain, at Regenicin's sole expense, any consent required as a condition to the assignment of the California Agreement, the California Amendment, the Cincinnati/SHC Agreement and the Cincinnati/SHC Amendment.

5.6 LWI shall send invoices to Regenicin for all expenses related to the prosecution and maintenance of Patent Rights.

5.7 LWI shall send invoices to Regenicin for all expenses related to the maintenance of the Licenses, including, without limitation, the license maintenance fee of Article 6 of the California Agreement.

## **Article 6. Payments**

6.1 Regenicin shall pay to LWI \$3,000,000 (three million dollars) as consideration for Current Know-How and other value transferred or to be transferred by Lonza to Regenicin.

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

6.2 Regenicin shall pay to LWI \$2,000,000 (two million dollars) upon approval by the United States Food and Drug Administration of the commercial sale of the Contract Product as the purchase price of the outstanding capital stock of Cutanogen Corporation transferred to Regenicin under the Stock Purchase Agreement in accordance with paragraph 9.1 below.

6.3 Regenicin shall pay to LWI 33% (thirty three percent) of any money received by Lonza or its affiliates during the term of this Agreement as a result of the AFIRM grant application in consideration for the development of the Contract Product conducted by L WI, and the transfer of the results thereof to Regenicin in accordance with paragraph 4.3 above.

6.4 Regenicin shall pay to L WI 33% (thirty three percent) of any money received by Lonza or its affiliates during the term of this Agreement as a result of any other grant application(s), including, but not limited to, as a result of any \* grant application, in consideration for the development of the Contract Product to be conducted by L WI, and the results thereof to be transferred to Regenicin in accordance with paragraph 4.4 above, with such payment to be made upon receipt of such grant.

6.5 Regenicin shall be responsible for any milestone payments that are owed, whether upon execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below or otherwise, as well as any milestone payments that, but for this Agreement, would not have been owed by L WI to one or more, including all, former owners of Cutanogen Corporation, including, without limitation, Stephen Boyce, the University of Cincinnati and the Shriners Hospital for Children. Milestone payments covered under this paragraph 6.5 include, without limitation, any milestone payments would have been owed under the Settlement Agreement and Release dated February 2, 2006 between the Shriners Hospital for Children, Cutanogen Corporation, the Shareholders of Cutanogen Corporation, and Cambrex Bio Science Walkersville, Inc. (Exhibit H).

## **Article 7. MANUFACTURING**

7.1 During the term of this Agreement and following execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below, L WI will retain the exclusive right to manufacture Contract Product at a customary margin level as more definitively set forth in the Manufacturing Agreement attached hereto as Exhibit I. Regenicin shall order amounts of Contract Product from L WI for clinical trial, and L WI shall manufacture Contract Product in accordance with the Manufacturing Agreement.

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

7.2 Regenicin shall pick up the Contract Product manufactured by L WI in accordance with Paragraph 7.1 above, and shall arrange for transportation from a facility designated by LWI to a facility designated by Regenicin for each delivery of Contract Product. All costs, taxes and other expenses relating to such delivery and transport, including, without limitation, insurance premiums, shall be at Regenicin's expense.

7.3 Title, and risk of loss or damage, to any shipment of Contract Product shall belong to Regenicin upon pick up of Contract Product by Regenicin in accordance with Paragraph 7.2 above.

7.4 If, at any time following execution of the Stock Purchase Agreement in accordance with paragraph 9.1 below, LWI is, for any reason, unable or unwilling to supply Regenicin's reasonable requirements for commercial supply of Contract Product and notifies Regenicin to that effect, LWI agrees that Regenicin may then have the Contract Product manufactured by one or more third parties to the extent necessary in order to permit Regenicin to obtain supply of its requirements of Contract Product (and the license grant set forth in paragraph 4.1 above shall be deemed to be modified to the extent necessary for such purpose).

#### **Article 8. Clinical Trials**

8.1. During the term of this Agreement, Regenicin shall prepare for and conduct pre-clinical and clinical trials. Regenicin shall use its best efforts during such trials to obtain approval from the FDA for the commercial sale of Contract Product.

8.2 LWI will support the pre-clinical and clinical trials conducted by Regenicin in accordance with paragraph 8.1 above by providing Current Know-How and Future Know-How in accordance with Article 3 above.

#### **Article 9. Stock Purchase Agreement**

9.1 Upon payment by Regenicin to L WI of the milestone payments provided for in paragraphs 6.2 and 6.5 above, Regenicin and L WI shall execute the Stock Purchase Agreement attached hereto as Exhibit J. For the sake of clarity, the Stock Purchase Agreement shall not be effective until all of the milestones due under paragraphs 6.2 and 6.5 above are paid in full.

#### **Article 10. Distribution**

10.1 After execution of the Stock Purchase Agreement, L WI will retain exclusive distribution rights for the sale of the collagen sponge of the Contract Product to a third party in accordance with a Distribution Agreement to be negotiated by the parties in good faith. Under the Distribution Agreement, LWI will keep 15% of the sale price as a logistics/distribution fee. Any remaining profit from the sale of the collagen sponge will be split equally between the parties.

10.2 The Distribution Agreement will contain a grant by Regenicin to L WI of a worldwide, transferable, non-revocable license under intellectual property owned by or licensed to Regenicin enabling L WI to satisfy its obligations to manufacture Contract Product under paragraph 7.1 above and to distribute Contract Product under paragraph 10.1 above.

#### **Article 11. Payments**

11.1 Except for payment under paragraph 6.1, which is due concurrently with the execution hereof, all payments due in accordance with this agreement shall be made in United States dollars within thirty (30) days of the due date or, as the case maybe, of the invoice date. Invoices shall be sent to Regenicin and payments shall be made to L WI at the addresses provided in paragraph 15.5 below.

#### **Article 12. Confidentiality**

12.1 Each party acknowledges and agrees that the other party (hereinafter the "Donor Party") owns certain confidential information regarding the Contract Product.

12.2 Confidential Information shall mean all information regarding the Contract Product that is hereafter received by a party to this Agreement (hereinafter the "Receiving Party") from the Donor Party, except that which:

(a) was in the public domain prior to the receipt under this Agreement, or thereafter becomes part of the public domain through no fault of the Receiving Party; or

(b) the Receiving Party can show, by credible written records, was in its possession at the time of receipt under this Agreement; or

(c) is received by the Receiving Party from a third party that is not under an obligation to the Donor Party to maintain the information in confidence.

12.3 All Confidential Information received under this Agreement shall be maintained by the Receiving Party in confidence and shall not be disclosed to any other person or entity without prior written approval of the Donor Party, except as is necessary for the Receiving Party to carry out its obligations under this Agreement.

12.4 All physical material containing Confidential Information shall be returned to the Donor Party prior to or immediately upon any termination of this Agreement, provided however, that the Receiving Party may retain one copy of written materials containing Confidential Information strictly for use as a record of information disclosed by the Donor Party, and to be used for no other purpose without the Donor Party's express written consent.

12.5 The Receiving Party hereby indemnifies and holds harmless the Donor Party against any loss resulting from unauthorized disclosure or use of the Confidential Information by the Receiving Party, its agents, or others to whom the Confidential Information has been disclosed by the Receiving Party pursuant to this Agreement.



### **Article 13. Term And Termination**

13.1 Unless otherwise terminated as provided hereunder, this Agreement shall become effective in accordance with paragraph 2.1 and remain in force from its Effective Date until execution of the Stock Purchase Agreement in accordance with Article 9.1 above.

13.2 In the event either party fails or refuses to perform any of its obligations hereunder (hereafter the Defaulting Party), the other party (hereafter the Terminating Party) may, without waiving any other rights, terminate this agreement.

13.3 If the Terminating Party wishes to terminate this agreement in accordance with paragraph 13.2 above, the Terminating Party shall first provide the Defaulting Party with written notice specifying the particulars of such failure or refusal. This Agreement shall terminate thirty (30) days after receipt of such notice by the Defaulting Party unless, within such thirty (30) day period, the default is fully remedied. Notwithstanding the foregoing, this Agreement may be terminated immediately (i) by the non-Defaulting Party in the event the Defaulting Party breaches paragraph 12 above or (ii) by Lonza in the event Regenicin breaches paragraph 11.1.

13.4 Termination of this Agreement shall not relieve either party to this Agreement of its obligations to make any payment that accrue hereunder prior to such termination, or of its obligations of confidentiality in accordance with Article 12 above.

13.5 In the event this Agreement is terminated earlier than provided for in paragraph 13.1 above by either party for any reason, any money transferred to L WI by Regenicin in accordance with Article 6 above shall be non-refundable.

13.6 In the event this Agreement is terminated earlier than provided for in paragraph 13.1 above by either party for any reason, Regenicin shall return all Current Know-How and Future Know-How to LWI, and will not use Current Know-How or Future Know-How for any purpose.

### **Article 14. Infringement and Indemnity**

14.1 LWI represents to Regenicin that, at the time this Agreement is entered into, LWI has no knowledge of any proprietary right that is owned by a third party that would be infringed by Regenicin's sale or use of Contract Product pursuant to this Agreement. However, L WI does not represent or warrant that Regenicin will not be subject to claims by a third party for infringement of a third party's proprietary rights of which L WI is unaware at the time this Agreement.

14.2 Regenicin agrees to hold harmless, defend and indemnify LWI against all damage, claim, expense and liability, including attorney fees, arising in any way from (i) the offering to sell, sale, or use of Contract Product by Regenicin or its agents or (ii) any actions whatsoever taken by Regenicin, its affiliates, or any of its or its affiliates' respective officers, directors, employees, agents, consultants, independent contractors or representatives in connection with this Agreement, the Contract Product, or Lonza's (or its affiliates') relationship with Regenicin.

**Article 15. Miscellaneous**

15.1 This Agreement shall be governed by and construed in accordance with the laws of The State of New York, without regard to its conflicts of laws rules.

15.2 This Agreement may only be amended in writing signed by both parties. There are no other understandings, agreements or representations, express or implied, not specified herein. If any provision of this Agreement is held to be unenforceable, such provision shall not render this Agreement or any other provision thereof unenforceable. In the event a provision of this Agreement is held to be unenforceable, the parties shall negotiate in good faith so that such unenforceable provision may be replaced by another provision of similar, but enforceable, effect. If such a replacement is not possible or cannot be agreed upon, the parties will negotiate in good faith so that the value of this Agreement to both parties remains the same despite the loss of the provision held to be unenforceable.

15.3 Regenicin shall not use the name Lonza or L WI or the trade name of a Lonza or L WI product without the express written consent ofLWI.

15.4 This Agreement shall not be assigned by either party to this Agreement to a third party without the written consent of the other party to this Agreement, such consent not to be unreasonably withheld.

15.5 Any notice required to be given under this Agreement shall be in writing, and shall be deemed to have been received on the day the notice has been transmitted by facsimile to the correct facsimile number, or three days after deposit in the mail, postage prepaid for first class mail, whichever occurs first. All mail shall be addressed as follows:

If to Regenicin:  
Regenicin, Inc.  
10 High Court  
Little Falls, NJ 07424  
Attn: Randal McCoy

If to LWI:  
L onza Walkersville, Inc.  
8830 Biggs Ford Road  
Walkersville, MD 21793  
Attn: David Smith

With a copy to:  
Stevens & Lee  
100 Lenox Drive, Suite 200  
Lawrenceville, NJ 08648  
Attn: Richard J. Pinto, Esq.

With a copy to:  
Lonza America, Inc.  
25 Commerce Drive  
Allendale, NJ 07401  
Attn: General Counsel

or to such other address as may be specified from time to time in a written notice.

**[remainder of page intentionally left blank]**

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

Regenicin, Inc.

Lonza Walkersville, Inc.

By: /s/ Randall McCoy  
Title: Chief Executive Officer  
Date: 7/21/2010

By: /s/ RM Geier-Cibiw  
Title:  
Date: 7/21/2010

**Exhibit A - List of Patent Rights**

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit A - List of Patent Rights**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit B - Hourly Rate for calculation of cost of Future Know-How**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit C - AFIRM Grant Application**

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\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit D - The Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation.**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit E - The First Amendment to the Amended and Restated Exclusive License Agreement between The Regents of the University of California and Cutanogen Corporation.**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission



\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit F - The License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand.**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit G - Amendment to the License Agreement between Cutanogen Corporation on the one hand and the University of Cincinnati and Shriners Hospitals for Children on the other hand.**

\*

\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**Exhibit H - Settlement Agreement and Release dated February 2, 2006 between the Shriners Hospital for Children, Cutanogen Corporation, the Shareholders of Cutanogen Corporation, and Cambrex Bio Science Walkersville, Inc.**

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\* The confidential portion has been omitted and filed separately with the Securities and Exchange Commission

## Exhibit I - Manufacturing Agreement

### MANUFACTURING SERVICES AGREEMENT

This Manufacturing Services Agreement (the "Agreement") is made as of [INSERT DATE], (the "Effective Date") between Lonza Walkersville, Inc., a Delaware corporation having its principal place of business at 8830 Biggs Ford Road, Walkersville, Maryland 21793 ("LWI"), and [NAME], [alan] [State of formation, if an entity] [corporation / partnership / limited liability company / limited liability partnership / individual], having an [office / address] at [address] ("CLIENT") (each of LWI and CLIENT, a "Party" and, collectively, the "Parties").

#### RECITALS

- A. LWI operates a multi -client production facility located at 8830 Biggs Ford Road, Walkersville, Maryland 21793 (the "Facility").
  - B. CLIENT desires to have L WI produce a product containing human cells and intended for therapeutic use in humans, and L WI desires to produce such product.
  - C. CLIENT desires to have L WI conduct work according to individual Statement of Work, as further defined in Section 1.32 below.
- NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants hereinafter set forth, L WI and CLIENT, intending to be legally bound, hereby agree as follows:

#### AGREEMENT

##### 1. DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

- 1.1. "Acceptance Period" shall have the meaning set forth in Section 5.2.2.
- 1.2. "Affiliate" means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means direct or indirect ownership of more than fifty percent (50%) of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.
- 1.3. "Batch" means a specific quantity of Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture
- 1.4. "Batch Record" means the production record pertaining to a Batch.

- 1.5. "cGMP" means the regulatory requirements for current good manufacturing practices promulgated by the FDA under 21 CFR Parts 210 and 211, as amended from time to time.
- 1.6. "Change Order" has the meaning set forth in Section 2.2.
- 1.7. "CLIENT Development Materials" has the meaning set forth in Section 2.3.
- 1.8. "CLIENT Inventions" means any know-how or inventions, whether or not patentable, conceived, developed or reduced to practice by CLIENT on or before the Effective Date.
- 1.9. "CLIENT Materials" means the CLIENT Development Materials and the CLIENT Production Materials.
- 1.10. "CLIENT Personnel" has the meaning set forth in Section 4.8.1.
- 1.11. "CLIENT Production Materials" has the meaning set forth in Section 4.2.
- 1.12. "Commencement Date" means the date set forth in the Statement of Work, based on a Draft Plan, for the commencement of the production of the Product.
- 1.13. "Confidential Information" has the meaning set forth in Section 10.1.
- 1.14. "Disapproval Notice" shall have the meaning set forth in Section 5.2.2.
- 1.15. "Draft Plan" shall have the meaning set forth in Section 4.1.
- 1.16. "FDA" means the U.S. Food and Drug Administration, and any successor agency thereof.
- 1.17. "First Statement of Work" has the meaning set forth in the definition of Statement of Work.
- 1.18. "Intellectual Property" means all worldwide patents, copyrights, trade secrets, know-how and all other intellectual property rights, including all applications and registrations with respect thereto, but excluding all trademarks, trade names, service marks, logos and other corporate identifiers.
- 1.19. "LWI Inventions" means any know-how, media, assays, methods or other inventions, whether or not patentable, conceived, developed or reduced to practice by LWI: (a) on or before the Effective Date; or (b) in connection with the performance of the Statement of Work or the Draft Plan.
- 1.20. "LWI Operating Documents" means the standard operating procedures, standard manufacturing procedures, raw material specifications, protocols, validation documentation, and supporting documentation used by L WI, such as environmental monitoring, for operation and maintenance of the Facility and L WI equipment used in the process of producing the Product, excluding any of the foregoing that are unique to the manufacture of Product.

- 1.21. "LWI Parties" has the meaning set forth in Section 15.2.
- 1.22. "Master Production Record" means the documentation developed by L WI that contains a detailed description of a Process and any other instructions to be followed by L WI in the production of a Product.
- 1.23. "Materials" means all raw materials and supplies to be used in the production of a Product.
- 1.24. "Process" means the manufacturing process for a Product developed by L WI pursuant to the terms of this Agreement.
- 1.25. "Product" has the meaning set forth in a Statement of Work.
- 1.26. "Product Warranties" means those warranties as specifically stated in Section 5.2.2.
- 1.27. "Production Term" shall have the meaning set forth in Section 4.4.
- 1.28. "Quality Agreement" means the Quality Agreement entered into by the Parties simultaneously with the execution hereof relating to a Product.
- 1.29. "Regulatory Approval" means the approval by the FDA to market and sell the Product in the United States.
- 1.30. "SOP" means a standard operating procedure.
- 1.31. "Specifications" means the Product specifications set forth in the Statement of Work or as modified by the Parties in connection with the production of a particular Batch of Product hereunder.
- 1.32. "Statement of Work" means a plan to develop a Process or Product that is attached hereto as Appendix A or 111ter becomes attached through an amendment by the Parties. The first Statement of Work, which is attached hereto, is numbered Appendix A-I and is hereby incorporated and made a part of this Agreement (the "First Statement of Work"). It is contemplated that each separate project shall have its own Statement of Work. As each subsequent Statement of Work is agreed to by the Parties, each shall state that it is to be incorporated and made a part of this Agreement and shall be consecutively numbered as A-2, A-3, etc.
- 1.33. "Technology Transfer" means the transfer of documentation, specifications, and production process by CLIENT to LWI for the development of the Master Production Record for the manufacturing of the Product specifically for the CLIENT.
- 1.34. "Third Party" means any party other than L WI, CLIENT or their respective Affiliates.

## **2. STATEMENTS OF WORK - PROCESS AND PRODUCT DEVELOPMENT; TECHNOLOGY TRANSFER; PROCESS OR PRODUCT MANUFACTURE**

2.1 Statement of Work. Prior to performing any Process or Product development, Technology Transfer, or Process or Product manufacture, the Parties will collaborate to develop a Statement of Work, describing the activities to be performed by the Parties, or to be subcontracted by LWI to Third Parties. Once agreed to by the Parties, the Statement of Work shall be executed by each of the Parties and appended hereto as part of Appendix A. In the event of a conflict between the terms and conditions of this Agreement and any Statement of Work, the terms and conditions of this Agreement shall control.

2.2 Modification of Statement of Work. Should CLIENT want to change a Statement of Work or to include additional services to be provided by L WI, CLIENT may propose to L WI an amendment to the Statement of Work with the desired changes or additional services ("Change Order"). If LWI determines that it has the resources and capabilities to accommodate such Change Order, L WI will prepare a modified version of the Statement of Work reflecting such Change Order (including, without limitation, any changes to the estimated timing, estimated charges or scope of a project) and will submit such modified version of the Statement of Work to CLIENT for review and comment. The modified Statement of Work shall be binding on the Parties only if it refers to this Agreement, states that it is to be made a part thereof, and is signed by both Parties. Whereafter such modified version of the Statement of Work will be deemed to have replaced the prior version of the Statement of Work. Notwithstanding the foregoing, if a modified version of the Statement of Work is not agreed to by both Parties, the existing Statement of Work shall remain in effect.

2.3 CLIENT Deliverables. Within the time period specified in a Statement of Work, CLIENT will provide L WI with ( a) the materials listed in the Statement of Work for which CLIENT is responsible for delivering to L WI, and any handling instructions, protocols, SOPs and other documentation necessary to maintain the properties of such materials for the performance of the Statement of Work, and (b) any protocols, SOPs and other information and documentation in possession or control of CLIENT and necessary for the performance of the Statement of Work, and for the preparation of the Master Production Record in conformance with cGMP, including, without limitation, process information, SOPs, development data and reports, quality control assays, raw material specifications (including vendor, grade and sampling/testing requirements), product and sample packing and shipping instructions, and product specific cleaning and decontamination information, (collectively, the "CLIENT Development Materials").

2.4 Performance by LWI. Subject to the provision by CLIENT of the CLIENT Development Materials pursuant to Section 2.3, LWI will use commercially reasonable efforts to perform, directly or, subject to the terms of the Statement of Work or approval by CLIENT (such approval not to be unreasonably withheld), through a Third Party contractor, the work described in a Statement of Work in a professional and workmanlike manner in accordance with the terms of this Agreement. L WI will use commercially reasonable efforts promptly to notify CLIENT of any material delays that arise during the performance of the Statement of Work.

### 3. TECHNOLOGY TRANSFER

3.1 Based on the information provided by CLIENT and including process changes developed by L WI pursuant to any applicable Statement of Work, L WI will prepare the Master Production Record for the Process in accordance with the schedule set forth in the Statement of Work. CLIENT will inform L WI of any specific requirements CLIENT may have relating to the Master Production Record, including, without limitation, any information or procedures CLIENT wishes to have incorporated therein. If L WI intends to include in the Master Production Record the use of any assay, medium, or other technology that is not commercially available, L WI will inform CLIENT of such intention and the Parties will meet to discuss and attempt to agree in good faith on the terms of use of such non-commercially available materials or technology in the Process.

3.2 CLIENT will cooperate with L WI to assist L WI to develop the Master Production Record and Process, including, without limitation, by providing L WI with additional information and procedures as may be required to create the Master Production Record, Process, and/or any of the following: (i) manufacturing process information, SOPs, development reports, (ii) quality control assays, (iii) raw material specifications (including vendor, grade and sampling/testing requirements), (iv) Product and sample packing and shipping instructions, (v) Product specific cleaning and decontamination information.

3.3 L WI will deliver a draft version of the Master Production Record to CLIENT for its review and approval in accordance with the schedule set forth in the Statement of Work. CLIENT will notify L WI in writing of any objections it has to the draft Master Production Record, and upon such notification, representatives of L WI and CLIENT will meet promptly to resolve such objections. Upon CLIENT's written acceptance of the draft Master Production Record, or in the event that CLIENT does not submit a written notice setting forth CLIENT's objections to the draft Master Production Record within ten (10) days following receipt of such draft by CLIENT, such draft will be deemed approved by CLIENT.

3.4 The Process, Master Production Record, Specifications, and any improvements or modifications thereto developed during the term of this Agreement, but excluding any L WI Operating Documents, L WI Inventions or L WI Confidential Information included in any of the foregoing, will be deemed CLIENT Confidential Information and subject to the provisions set forth in Article 10. CLIENT shall be permitted to use the Process and/or the Master Production Record to manufacture and sell Product; provided, however, that if the Process and/or the Master Production Record incorporates or contains any L WI Intellectual Property or L WI Confidential Information, prior to any disclosure of such L WI Intellectual Property or L WI Confidential Information to, or use by, a Third Party manufacturer, CLIENT shall obtain L WI's written consent to such disclosure.



#### **4. MANUFACTURE OF PRODUCT; ORDER PROCESS; DELIVERIES**

4.1 Draft Plan. Together with the draft version of the Master Production Record described in Section 3.3 above, L WI will deliver to CLIENT for review and comment, a proposed draft plan describing the activities to be performed by L WI, or to be subcontracted by LWI to Third Parties, in the production of a Product (the "Draft Plan"). Once LWI delivers to CLIENT the proposed Draft Plan, the parties will meet to decide whether to issue a new Statement of Work pursuant to Section 2.1, or to modify an existing Statement of Work pursuant to Section 2.2, based on that Draft Plan and any agreed upon modifications.

4.2 CLIENT Deliverables. Within any time period specified in the Draft Plan and agreed to in any applicable Statement of Work, CLIENT will provide LWI with (a) the materials listed in the Statement of Work required to be supplied by CLIENT for the production of the Product, and any handling instructions, protocols, SOPs and other documentation necessary to maintain the properties of such materials for the performance of the Draft Plan (collectively, the "CLIENT Production Materials").

4.3 Commencement Date. The Statement of Work based on a Draft Plan will include a Commencement Date agreed upon by the Parties.

4.4 Manufacture by L WI. During the time period specified in any Statement of Work during which Product will be manufactured (the "Production Term"), L WI will use commercially reasonable efforts to manufacture, package, ship, handle quality assurance and quality control for the Product, all as set forth in the Statement of Work, and to deliver to CLIENT the quantities of Product requested by CLIENT in the Statement of Work~ all in accordance with the terms set forth in Section 4.5 below.

4.5 Packaging and Shipping. L WI will package and label the Product for shipment in accordance with the Master Production Record and LWI's standard practices in effect at the time of performance by LWI. LWI will ship the Product FOB Shipping Point delivered at the Facility to a common carrier designated by CLIENT to L WI in writing not less than ten days prior to the applicable delivery date unless otherwise agreed to in a Statement of Work. CLIENT will provide to L WI its account number with the selected carrier and will pay for all shipping costs in connection with each shipment of Product. Each shipment will be accompanied by the documentation listed in the Draft Plan. LWI will use commercially reasonable efforts to deliver each shipment of Product to CLIENT on the requested delivery date for such shipment. L WI will promptly notify CLIENT if L WI reasonably believes that it will be unable to meet a delivery date. CLIENT shall be required to take delivery of a Batch of Product within thirty (30) days after acceptance of such Batch in accordance with Section 5.2 (the "Delivery Period").

4.6 Quality Agreement. Upon the decision to manufacture a Product according to a Draft Plan, the Parties shall enter into a separate Quality Agreement, in the form attached hereto, setting forth the terms for Product quality, quantity, price, and any other terms necessary for such agreements. Such Quality Agreement shall be separately appended to this Agreement.

4.7 Records. L WI will maintain accurate records for the production of the Product, as required by applicable laws and regulations. LWI will retain possession of the Master Production Record, all Batch Records and L WI Operating Documents, and will make copies thereof available to CLIENT upon CLIENT's request and at CLIENT's expense. L WI Operating Documents will remain LWI Confidential Information. CLIENT will have the right to use and reference any of the foregoing in connection with a filing for Regulatory Approval of the Product or as otherwise authorized by the Agreement.

4.8 CLIENT Access.

4.8.1 CLIENT's employees and agents (including its independent contractors) (collectively, "CLIENT Personnel") may participate in the production of the Product only in such capacities as may be approved in writing in advance by L WI. CLIENT Personnel working at the Facility are required to comply with LWI's Operating Documents and any other applicable LWI facility and/or safety policies. For the avoidance of doubt, CLIENT Personnel may not physically participate in the production or manufacture of any Product that may be used in or on humans.

4.8.2 CLIENT Personnel working at the Facility will be and remain employees of CLIENT, and CLIENT will be solely responsible for the payment of compensation for such CLIENT Personnel (including applicable Federal, state and local withholding, FICA and other payroll taxes, workers' compensation insurance, health insurance, and other similar statutory and fringe benefits). CLIENT covenants and agrees to maintain workers' compensation benefits and employers' liability insurance as required by applicable Federal and Maryland laws with respect to all CLIENT Personnel working at the Facility.

4.8.3 CLIENT will pay for the actual cost of repairing or replacing to its previous status (to the extent that LWI determines, in its reasonable judgment, that repairs cannot be adequately effected) any property of LWI damaged or destroyed by CLIENT Personnel, provided CLIENT shall not be liable for repair or replacement costs resulting from ordinary wear and tear.

4.8.4 CLIENT Personnel visiting or having access to the Facility will abide by L WI standard policies, operating procedures and the security procedures established by L WI. CLIENT will be liable for any breaches of security by CLIENT Personnel. In addition, CLIENT will reimburse L WI for the cost of any lost security cards issued to CLIENT Personnel, at the rate of \$50 per security card. All CLIENT Personnel will agree to abide by L WI policies and SOPs established by L WI, and will sign an appropriate confidentiality agreement.

4.8.5 CLIENT will indemnify and hold harmless L WI from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) arising out of any injuries suffered by CLIENT Personnel while at the Facility or elsewhere, except to the extent caused by the gross negligence or willful misconduct on the part of any LWI Party.

4.9 Disclaimers. CLIENT acknowledges and agrees that L WI Parties will not engage in any Product refinement or development of the Product, other than as expressly set forth in this Agreement and the Statement of Work. CLIENT acknowledges and agrees that L WI Parties have not participated in the invention or testing of any Product, and have not evaluated its safety or suitability for use in humans or otherwise.

## 5. PRODUCT WARRANTIES; ACCEPTANCE AND REJECTION OF PRODUCTS

5.1 Product Warranties. L WI warrants that any Product manufactured by L WI pursuant to this Agreement, at the time of delivery pursuant to Section 1: (a) conforms to the Specifications; (b) was manufactured in accordance with the Master Production Record; and (c) was manufactured in accordance with cGMP.

5.2 Approval of Shipment.

5.2.1 When the Product ordered by CLIENT is ready for delivery, L WI will notify CLIENT and supply CLIENT with the required documentation set forth in the Draft Plan.

5.2.2 .. Within ten (10) calendar days after CLIENT's receipt of such documentation regarding such Product (the "Acceptance Period"), Client shall determine by review of such documentation whether or not the given Batch conforms to the product warranties set forth in Section 5.1 above ("Product Warranties"). If CLIENT asserts that the Product does not comply with the Product Warranties set forth in Section 5.1 above, CLIENT will deliver to L WI, in accordance with the notice provisions set forth in Section 17.4 hereof, written notice of disapproval (the "Disapproval Notice") of such Product, stating in reasonable detail the basis for such assertion of non-compliance with the Product Warranties. If a valid Disapproval Notice is received by L WI during the Acceptance Period, then L WI and CLIENT will provide one another with all related paperwork and records (including, but not limited to, quality control tests) relating to both the production of the Product and the Disapproval Notice. If a valid Disapproval Notice is not received during the Acceptance Period, the Product will be deemed accepted and ready for shipment. Upon acceptance, the Product shall be delivered to CLIENT and CLIENT shall accept delivery thereof, within 10-days after such acceptance. Title and risk of loss to such Product shall pass to CLIENT at the time of delivery to the Common carrier pursuant to Section 4.5.

5.3 Dispute Resolution. L WI and CLIENT will attempt to resolve any dispute regarding the conformity of a shipment of Product with the Product Warranties. If such dispute cannot be settled within 30 days of the submission by each Party of such related paperwork and records to the other Party, and if the Product is alleged not to conform with the Product Warranties set forth in Section 5.1(a), then CLIENT will submit a sample of the Batch of the disputed shipment to an independent testing laboratory of recognized repute selected by CLIENT and approved by L WI (such approval not to be unreasonably withheld) for analysis, under quality assurance approved procedures, of the conformity of such shipment of Product with the Specifications. The costs associated with such analysis by such independent testing laboratory will be paid by the Party whose assessment of the conformity of the shipment of Product with the Specifications was mistaken.

#### 5.4 Remedies for Non-Conforming Product.

5.4.1 In the event that the Parties agree, or an independent testing laboratory determines, pursuant to Section 5.3, that a Batch of Product materially fails to conform to the Product Warranties due to the failure of: (a) LWI personnel properly to execute the Master Production Record, (b) LWI personnel to comply with cGMP, or (c) the Facility utilities, then, at CLIENT's request, LWI will produce for CLIENT sufficient quantities of Product to replace the nonconforming portion of such Batch of Product (the "Production Rerun"), in accordance with the provisions of this Agreement and at no additional cost to CLIENT.

5.4.2 In the event that the Parties agree, or an independent testing laboratory determines, pursuant to Section 5.3, that a Batch of Product materially fails to conform to the Product Warranties for any reason other than as set forth in Section 5.4.1, then LWI shall have no liability to CLIENT with respect to such Batch and LWI will, at CLIENT's request, produce for CLIENT a Production Rerun at CLIENT's expense.

5.4.3 CLIENT acknowledges and agrees that its sole remedy with respect to the failure of Product to conform with any of the Product Warranties is as set forth in this Section 5.4, and in furtherance thereof, Client hereby waives all other remedies at law or in equity regarding the foregoing claims.

### 6. DAMAGE OR DESTRUCTION OF MATERIALS AND/OR PRODUCT

6.1 Remedies. If during the manufacture of Product pursuant to this Agreement, Product and/or Materials are destroyed or damaged by LWI Personnel, and such damage or destruction resulted from LWI's failure to execute the Process in conformity with the Master Production Record, then, except as provided in Section 6.2 below, LWI, as soon as it is commercially practicable to do so, will provide CLIENT with additional Product production time equal to the actual time lost because of the destruction or damage of the Product and/or Materials and will replace such Product and/or Materials at no additional cost to CLIENT. CLIENT acknowledges and agrees that its sole remedy with respect to damaged or destroyed Materials and/or Product (except for the nonconformity of shipped Product described in Section 5) is as set forth in this Section 6.1, and in furtherance thereof, CLIENT hereby waives all other remedies at law or in equity regarding the foregoing claims.

6.2 Limitations. Notwithstanding anything to the contrary set forth in the preceding Section 6.1, if during the manufacture of Product pursuant to this Agreement, Product or Materials are destroyed or damaged by LWI Personnel while LWI Personnel were acting at the direction of CLIENT Personnel, then LWI will have no liability to CLIENT as the result of such destruction or damage.

### 7. STORAGE OF MATERIALS

7.1 Pre-Production. LWI will store at the expense of CLIENT any CLIENT Materials, equipment or other property delivered pursuant to the Statement of Work or the Draft Plan to the Facility by CLIENT more than 30 days prior to the Commencement Date. The storage rates will be set forth in the Statement of Work and may be amended from time to time by LWI. No storage fees will be charged during the period starting 30 days prior to the Commencement Date and ending upon the expiration or termination of the Production Term.

7.2 Post-Production. LWI will store at the Facility free of charge any in-process materials, CLIENT Materials, equipment and other CLIENT property (other than Product manufactured hereunder) that remains at the Facility on the date of expiration or termination of the Production Term (collectively "Remaining CLIENT Property"), for up to 15 calendar days. If CLIENT has not provided any instructions as to the shipment or other disposition of Remaining CLIENT Property prior to the expiration of such fifteen (15)-day period, LWI may, in its sole discretion, destroy such Remaining CLIENT Property, or continue to store such Remaining CLIENT Property at the Facility or elsewhere. In the event that LWI continues to store such Remaining CLIENT Property, CLIENT will pay to LWI a storage charge at LWI's then-standard storage rates for the period beginning on the sixteenth (16th) day after the expiration or termination of the Production Term through the date that the storage terminates.

7.3 Product. Notwithstanding the foregoing, if CLIENT fails to take delivery of a Product within the applicable Delivery Period as required by Section 4.5, CLIENT will pay to LWI a storage charge at three times LWI's then standard storage rate, which shall begin accruing on the first day following the expiration of the applicable Delivery Period.

## **8. REGULATORY MATTERS**

8.1 Permits and Approvals. During the Production Term, LWI will use commercially reasonable efforts to maintain any licenses, permits and approvals necessary for the manufacture of the Product in the Facility. LWI will promptly notify CLIENT if LWI receives notice that any such license, permit, or approval is or may be revoked or suspended.

8.2 Inspections/Quality Audit by CLIENT. Up to two times during the Production Term and upon not less than 30 days' prior written notice, LWI will permit CLIENT to inspect and audit the parts of the Facility where the manufacture of the Product is carried out in order to assess LWI's compliance with cGMP, and to discuss any related issues with LWI's management personnel. CLIENT Personnel engaged in such inspection will abide by the terms and conditions set forth in Sections 4.8.4 and 10.

8.3 Inspections by Regulatory Agencies. LWI will allow representatives of any regulatory agency to inspect the relevant parts of the Facility where the manufacture of the Product is carried out and to inspect the Master Production Record and Batch Records to verify compliance with cGMP and other practices or regulations and will promptly notify CLIENT of the scheduling of any such inspection relating to the manufacture of Product. LWI will promptly send to CLIENT a copy of any reports, citations, or warning letters received by CLIENT in connection with an inspection of a regulatory agency to the extent such documents relate to or affect the manufacture of the Product.

## 9. FINANCIAL TERMS

9.1 **Payments.** CLIENT will make payments to L WI in the amounts and on the dates set forth in the Statement of Work. In the event that CLIENT has not paid an invoice within thirty (30) business days of the applicable due date (as established by Section 9.3), CLIENT's failure shall be considered a material breach under Section 14.2, subject to the cure provisions set forth therein. Further, in addition to all other remedies available to L WI, in the event that CLIENT has not paid an invoice within sixty (60) business days of the applicable due date (as established by Section 9.3), L WI may elect to suspend the provision of all or a portion of the services under this Agreement, provided that CLIENT shall remain liable for all fees owed pursuant to the Statement of Work during any such suspension.

9.2 **Security Deposit.** The Security Deposit, as defined in the Statement of Work, will be returned to CLIENT within 60 days after the date of expiration or termination of this Agreement, if CLIENT has paid all fees, charges, or other payments due in connection with charges incurred prior to the expiration or termination of this Agreement, including, but not limited to, charges for lost, destroyed, stolen or damaged property of LWI (all such fees, charges, or other payments being called "Obligations"). If any Obligations remain outstanding after the date of expiration or termination of this Agreement, then L WI shall be entitled to apply the Security Deposit against the payment of such Obligations. The amount of the Security Deposit remaining, if any, after such application will be returned to CLIENT. CLIENT shall remain liable to L WI for any deficiencies remaining after the application of the Security Deposit against the Obligations.

9.3 **Invoices.** Within 30 days of the end of each month during which charges were incurred, LWI will provide CLIENT with an invoice setting forth a detailed account of any fees, expenses, or other payments payable by CLIENT under this Agreement for the preceding month. The amounts set forth in each such invoice will be due and payable within 30 days of receipt of such invoice by CLIENT.

9.4 **Taxes.** CLIENT agrees that it is responsible for and will pay any sales, use or other taxes (the "Taxes") resulting from L WI's production of Product under this Agreement (except for income or personal property taxes payable by LWI). To the extent not paid by CLIENT, CLIENT will indemnify and hold harmless the LWI Parties from and against any and all penalties, fees, expenses and costs whatsoever in connection with the failure by CLIENT to pay the Taxes. L WI will not collect any sales and use taxes from CLIENT in connection with the production of any Product hereunder if CLIENT provides to L WI the appropriate valid exemption certificates.

9.5 **Interest.** Any fee, charge or other payment due to LWI by CLIENT under this Agreement that is not paid within 30 days after it is due will accrue interest on a daily basis at a rate of 1.5% per month (or the maximum legal interest rate allowed by applicable law, if less) from and after such date.

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

9.6 Method of Payment. All payments to LWI hereunder by CLIENT will be in United States currency and will be by check, wire transfer, money order, or other method of payment approved by L WI. Bank information for wire transfers is as follows:

Mailing address for wire transfer payments: [TO BE PROVIDED]

9.7 Cost Adjustments. After the first anniversary of the Effective Date, LWI may annually adjust the various costs and rates set forth in the Statement of Work attached hereto to reflect changes in the cost of materials and/or labor rate paid by L WI in connection with the production of Product under this Agreement; provided, however, that any increase in labor rates shall not exceed any percentage increase in the US Consumer Price Index for the most recently published percentage change for the 12-month period preceding the applicable contract anniversary date. L WI agrees to provide CLIENT with written notice of any such cost adjustment.

## **10. CONFIDENTIAL INFORMATION**

10.1 Definition. "Confidential Information" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business, that has been disclosed by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement. Without limiting the foregoing, the terms of this Agreement will be deemed "Confidential Information" and will be subject to the terms and conditions set forth in this Article 10.

10.2 Exclusions. Notwithstanding the foregoing Section 10.1, any information disclosed by a Party to the other Party will not be deemed "Confidential Information" to the extent that such information:

- (a) at the time of disclosure is in the public domain;
- (b) becomes part of the public domain, by publication or otherwise, through no fault of the Party receiving such information;
- (c) at the time of disclosure is already in possession of the Party who received such information, as established by contemporaneous written records;
- (d) is lawfully provided to a Party, without restriction as to confidentiality or use, by a Third Party lawfully entitled to possession of such Confidential Information; or
- (e) is independently developed by a Party without use of or reference to the other Party's Confidential Information, as established by contemporaneous written records.

10.3 Disclosure and Use Restriction. Except as expressly provided herein, the Parties agree that for the term of the Agreement and the five-year period following any termination of the Agreement, each Party and its Affiliates will keep completely confidential and will not publish or otherwise disclose any Confidential Information of the other Party, its Affiliates or sublicensees, except in accordance with Section 10.4. Neither Party will use Confidential Information of the other Party except as necessary to perform its obligations or to exercise its rights under this Agreement.

10.4 Permitted Disclosures. Each receiving Party agrees to (i) institute and maintain security procedures to identify and account for all copies of Confidential Information of the disclosing Party and (ii) limit disclosure of the disclosing Party's Confidential Information to its U. S. and European Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors having a need to know such Confidential Information for purposes of this Agreement; provided that such U.S. and European Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors are informed of the terms of this Agreement and are subject to obligations of confidentiality, nondisclosure and non-use similar to those set forth herein.

10.5 Government-Required Disclosure. If a duly constituted government authority, court or regulatory agency orders that a Party hereto disclose information subject to an obligation of confidentiality under this Agreement, such Party shall comply with the order, but shall notify the other Party as soon as possible, so as to provide the said Party an opportunity to apply to a court of record for relief from the order.

10.6 Publicity. Neither Party will refer to, display or use the other's name, trademarks or trade names confusingly similar thereto, alone or in conjunction with any other words or names, in any manner or connection whatsoever, including any publication, article, or any form of advertising or publicity, except with the prior written consent of the other Party.

## **11. INTELLECTUAL PROPERTY**

### **11.1 Ownership.**

11.1.1 As between the Parties, CLIENT shall own any and all inventions or discoveries that are (i) made, conceived or reduced to practice in the course of or resulting from this Agreement by either Party alone or the Parties jointly and (ii) applicable specifically only to the Product or the Process ("CLIENT New IP"). L WI hereby assigns to CLIENT all of L WI's right, title and interest in and to such CLIENT New IP.

11.1.2 As between the Parties, LWI shall own any and all inventions or discoveries that are (i) made, conceived or reduced to practice in the course of or resulting from this Agreement by L WI and (ii) capable of being applied to products or processes other than or in addition to the Product or the Process, and (iii) relates generally to L WI's business of producing biological materials ("LWINew IP"). CLIENT hereby assigns to LWI all of CLIENT's right, title and interest in and to such LWI New IP.

### **11.2 License Grants.**

11.2.1 During the term of this Agreement, CLIENT hereby grants to LWI a fully paid, non-exclusive license under any and all CLIENT Intellectual Property that is necessary for L WI to perform its obligations under this Agreement for the sole and limited purpose of L WI's performance of its obligations under this Agreement, including, without limitation, the development of the Process and the manufacture of Product for CLIENT.



11.2.2 LWI hereby grants to CLIENT an irrevocable, fully paid, non-exclusive license, with the right to grant and authorize sublicenses, under any and all (i) L WI Intellectual Property (including L WI New IP) that L WI incorporates into the Process, to make, have made, use, sell, offer for sale, have sold and import the Product, and (ii) know-how included in the L WI New IP and not claimed in a patent or patent application, to use for any purpose.

11.3 Further Assurances. Each Party agrees to take all necessary and proper acts, and will cause its employees, Affiliates, contractors, and consultants to take such necessary and proper acts, to effectuate the ownership provisions set forth in this Article 11.

11.4 Prosecution of Patents.

11.4.1 LWI will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming L WI Inventions at L WI's expense. CLIENT will cooperate with LWI to file, prosecute and maintain patent applications and patents claiming LWI Inventions, and will have the right to review and provide comments to L WI relating to such patent applications and patents.

11.4.2 CLIENT will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming CLIENT Inventions at CLIENT's expense. LWI will cooperate with CLIENT to file, prosecute and maintain patent applications and patents claiming CLIENT Inventions, and will have the right to review and provide comments to CLIENT relating to such patent applications and patents.

## **12. REPRESENTATIONS AND WARRANTIES**

12.1 By CLIENT. CLIENT hereby represents and warrants to L WI that, to the best of its knowledge, (i) it has the requisite intellectual property and legal rights related to the CLIENT Deliverables and the Product to authorize the performance of LWI's obligations under this Agreement, and (ii) the performance of the Statement of Work and the production by L WI of the Product as contemplated in this Agreement will not give rise to a potential cause of action by a Third Party against LWI for infringement or another violation of intellectual property rights. Such representation and warranty will not apply to any production equipment supplied by L WI.

12.2 By LWI. LWI hereby represents and warrants to CLIENT that, to the best of its knowledge, (i) it has the requisite intellectual property rights in its equipment and Facility to be able to perform its obligations under this Agreement, and (ii) that L WI's use of its equipment and Facility as contemplated in this Agreement will not give rise to a potential cause of action by a Third Party against CLIENT for infringement or another violation of intellectual property rights.

### **13. DISCLAIMER; LIMITATION OF LIABILITY**

13.1 **DISCLAIMER.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, LWI MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, WITH RESPECT TO THE PRODUCTS, MATERIALS, AND SERVICES PROVIDED UNDER THIS AGREEMENT, AND LWI SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANT ABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE WITH RESPECT TO SUCH PRODUCTS, MATERIALS, OR SERVICES.

13.2 **Disclaimer of Consequential Damages.** IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

13.3 **Limitation of Liability.** BOTH PARTIES HEREBY AGREE THAT TO THE FULLEST EXTENT PERMITTED BY LAW, LWI'S LIABILITY TO CLIENT, FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT FROM ANY CAUSE OR CAUSES, INCLUDING, BUT NOT LIMITED TO, NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY, SHALL NOT EXCEED THE TOTAL CHARGES PAID BY CLIENT TO LWI DURING THE 12 (TWELVE) MONTHS PRECEDING THE EVENT GIVING RISE TO LIABILITY. TO THE EXTENT THAT THIS CLAUSE CONFLICTS WITH ANY OTHER CLAUSE, THIS CLAUSE SHALL TAKE PRECEDENCE OVER SUCH CONFLICTING CLAUSE. IF APPLICABLE LAW PREVENTS ENFORCEMENT OF THIS CLAUSE, THEN THIS CLAUSE SHALL BE DEEMED MODIFIED TO PROVIDE THE MAXIMUM PROTECTION FOR LWI AS IS ALLOWABLE UNDER APPLICABLE LAW.

### **14. TERM AND TERMINATION**

14.1 **Term.** The term of this Agreement will commence on the Effective Date and will continue until the fifth anniversary of the Effective Date unless terminated prior to that time or extended by the Parties.

14.2 **Termination for Material Breach.** Either Party may terminate this Agreement, by written notice to the other Party, for any material breach of this Agreement by the other Party, if such breach is not cured within thirty (30) days after the breaching Party receives written notice of such breach from the non-breaching Party; provided, however, that if such breach is not capable of being cured within such thirty-day period and the breaching Party has commenced and diligently continued actions to cure such breach within such thirty-day period, except in the case of a payment default, the cure period shall be extended to 180 days, so long as the breaching Party is making diligent efforts to do so. Such termination shall be effective upon expiration of such cure period.

### 14.3 Termination by Notice.

14.3.1 Without Cause. After the first anniversary of the Effective Date, either Party may terminate this Agreement by providing written notice of termination not less than six months in advance of the date of termination. For the avoidance of doubt, in the event of termination by CLIENT under this Section 14.3.1, CLIENT shall, at minimum, remain liable for all fees owed pursuant to any outstanding Statement of Work during such six-month period.

14.3.2 Termination of Clinical Trials. Either Party may terminate this Agreement if such Party receives notice that the production of Product hereunder or the clinical trials for which Product is being produced hereunder have been or will be suspended or terminated by the FDA (or other regulatory authority) by providing written notice of termination not less than 2 months in advance of the date of termination. For the avoidance of doubt, in the event of termination by CLIENT under this Section 14.3.2, CLIENT shall, at minimum, remain liable for all fees owed pursuant to any outstanding Statement of Work during such two-month period.

14.4 Termination by Insolvency. Either Party may terminate this Agreement upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within ninety (90) days of such appointment; (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within ninety (90) days of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, licenses of rights of "intellectual property" as defined therein.

### 14.5 Effects of Termination.

14.5.1 Accrued Rights. Termination of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to such termination. Such termination will not relieve a Party of obligations that are expressly indicated to survive the termination of this Agreement.

14.5.2 Disposition of Remaining CLIENT Property and Confidential Information. Upon termination or expiration of this Agreement, L WI will store any Remaining CLIENT Property as set forth in Section 7.2 and, at CLIENT's option, return or destroy any CLIENT Confidential Information in the possession or control of L WI. Likewise, CLIENT will, at L WI's option, return or destroy any L WI Confidential Information in the possession or control of CLIENT. Notwithstanding the foregoing provisions: (i) L WI may retain and preserve, at its sole cost and expense, samples and standards of each Product following termination or expiration of this Agreement solely for use in determining L WI's rights and obligations hereunder; and (ii) each Party may retain a single copy of the other Party's Confidential Information for documentation purposes only and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.

14.5.3 Security Deposits. Upon any termination of this Agreement by L WI pursuant to Section 14.2, LWI will have the right to retain the full amount of any Security Deposit paid to L WI pursuant to a Statement of Work, without limiting any of its rights in law or in equity under this Agreement.

14.5.4 Survival. Sections 1,3,4, 4.9, 7.2, 10, 11, 13, 14.4, 15, 16 and 17 of this Agreement, together with any appendices referenced therein, will survive any expiration or termination of this Agreement.

## **15. INDEMNIFICATION**

15.1 Indemnification of Client. LWI will indemnify CLIENT, its Affiliates, and their respective directors, officers, employees and agents, and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all liability suits, investigations, claims or demands (collectively, "Losses") to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: (a) any material breach by LWI of this Agreement, or (b) the gross negligence or willful misconduct on the part of one or more of the L WI Parties in performing any activity contemplated by this Agreement, except for those Losses for which CLIENT has an obligation to indemnify the L WI Parties pursuant to Section 15.2, as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses.

15.2 Indemnification of L WI. CLIENT will indemnify LWI and its Affiliates, and their respective directors, officers, employees and agents (the "LWI Parties"), and defend and hold each of them harmless, from and against any and all Losses to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: (a) any material breach by CLIENT of this Agreement, (b) the use or sale of Products, except to the extent such Losses arise out of or result from a breach by L WI of the Product Warranties, (c) the gross negligence or willful misconduct on the part of CLIENT or its Affiliates in performing any activity contemplated by this Agreement, or (d) the use or practice by LWI of any process, invention or other intellectual property supplied by CLIENT to LWI under this Agreement, except for those Losses for which L WI has an obligation to indemnify CLIENT pursuant to Section 15.1, as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses.

15.3 Indemnification Procedure.

15.3.1 An "Indemnitor" means the indemnifying Party. An "Indemnitee" means the indemnified Party, its Affiliates, and their respective directors, officers, employees and agents.

15.3.2 An Indemnitee which intends to claim indemnification under Section 15.1 or Section 15.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that in order for the Indemnitor to exercise such rights, such settlement shall not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

15.4 Insurance. CLIENT will maintain, at all times during the term of this Agreement and for five years thereafter, a products liability insurance policy (the "Insurance Policy"), with a per occurrence limit of at least five million dollars (\$5,000,000) and an aggregate limit of at least five million dollars (\$5,000,000), and will provide a Certificate of Insurance to LWI that the Insurance Policy has been endorsed to designate LWI as an additional insured. CLIENT will maintain the Insurance Policy with an insurance company having a minimum AM Best rating of A and that is licensed to do business in the State of Maryland. CLIENT will provide LWI with at least 30 days' written notice prior to termination of such Insurance Policy.

## **16. ADDITIONAL COVENANTS**

16.1 Non-Solicitation. During the term of this Agreement and for two (2) years thereafter, each of the Parties agrees not to seek to induce or solicit any employee of the other Party or its Affiliates to discontinue his or her employment with the other Party or its Affiliate in order to become an employee or an independent contractor of the soliciting Party or its Affiliate; provided, however, that neither Party shall be in violation of this Section 16.1 as a result of making a general solicitation for employees or independent contractors. For the avoidance of doubt, the publication of an advertisement shall not constitute solicitation or inducement.

16.2 Commercial Scale Manufacture. In the event that CLIENT desires to commence commercial scale manufacture of Product, the Parties agree to negotiate for the provision of such manufacturing services to CLIENT by L WI.

## **17. MISCELLANEOUS**

17.1 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

17.2 Force Majeure. Neither Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement) occasioned by any reason beyond the control and without the fault or negligence of the Party affected thereby, including, without limitation, an act of God, fire, flood, act of government or state, war, civil commotion, insurrection, acts of terrorism, embargo, sabotage, a viral, bacterial or mycoplasmal contamination which causes a shutdown of the Facility, prevention from or hindrance in obtaining energy or other utilities, a shortage of raw materials or other necessary components, labor disputes of whatever nature, or any other reason beyond the control and without the fault or negligence of the Party affected thereby (a "Force Majeure Event"). Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement as soon as it is commercially reasonable for the Party to do so. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable to fully perform its obligations under this Agreement. Each Party further agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as practicable (provided that in no event shall a Party be required to settle any labor dispute) and to give the other Party prompt written notice when it is again fully able to perform such obligations.

17.3 Condemnation. If the Facility is condemned or taken as a result of the exercise of the power of eminent domain or will be conveyed to a governmental agency having power of eminent domain under the threat of the exercise of such power (any of the foregoing, a "Condemnation"), then this Agreement will terminate as of the date on which title to the Facility vests in the authority so exercising or threatening to exercise such power and CLIENT will not have any right to the Condemnation proceeds.

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

17.4 Notices. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with documented evidence of transmission), to the addresses or facsimile numbers of the other Party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to LWI:

Lonza Walkersville, Inc.  
Attn: Vice President, Cell Therapy Bioservice  
8830 Biggs Ford Road  
Walkersville, Maryland 21793  
Fax: (301) 845-6099

With a copy to:

Assistant General Counsel  
Lonza America, Inc.  
90 BoroLine Road  
Allendale, NJ 07401  
Fax: (201) 696-3589

If to Client:

<insert full legal name of client company>  
Attn: <insert appropriate name>  
<insert street address>  
<insert city, state and zip code>  
Fax: <insert fax number>

**Either Party may change its address for notice by giving notice thereof in the manner set forth in this Section 17.4.**

17.5 Entire Agreement; Amendments. This Agreement, including the Appendices attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof and supersedes all prior agreements and understandings, oral and written, among the Parties with respect to the subject matter hereof. No terms, conditions, understandings or agreements purporting to amend, modify or vary the terms of this Agreement (including any Appendix hereto) shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.

17.6 Governing Law. This Agreement will be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to its conflicts of laws provisions.

17.7 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

17.8 Severability. If any part of this Agreement shall be found to be invalid or unenforceable under applicable law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

17.9 Titles and Subtitles. All headings, titles and subtitles used in this Agreement (including any Appendix hereto) are for convenience only and are not to be considered in construing or interpreting any term or provision of this Agreement (or any Appendix hereto).

17.10 Exhibits. All "RECITALS", "DEFINITIONS", exhibits and appendices referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.



\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

17.11 Pronouns. Where the context requires, (i) all pronouns used herein will be deemed to refer to the masculine, feminine or neuter gender as the context requires, and (ii) the singular context will include the plural and vice versa.

17.12 Assignment. This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld. Any permitted assignment of this Agreement by either Party will be conditioned upon that Party's permitted assignee agreeing in writing to comply with all the terms and conditions contained in this Agreement. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

17.13 Waiver. The failure of any Party at any time or times to require performance of any provision of this Agreement (including any Appendix hereto) will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any term, provision or condition contained in this Agreement (including any Appendix hereto), whether by conduct or otherwise, in anyone or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement (including any Appendix hereto).

17.14 Dispute Resolution. If the Parties are unable to resolve a dispute, despite its good faith efforts, either Party may refer the dispute to the Chief Executive Officer (or other designee) of each Party. In the event that no agreement is reached by the Chief Executive Officers (or other designees) with respect to such dispute within thirty (30) days after its referral to them, either Party may pursue any and all remedies available at law or in equity.

17.15 No Presumption Against Drafter. For purposes of this Agreement, CLIENT hereby waives any rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

**IN WITNESS WHEREOF, the parties have executed this Agreement as of the date last signed by the parties hereto.**

**Date**        **By:**  
                 **Name:**  
                 **Title:**

**Date**        **LONZA WALKERSVILLE, INC.**  
                 **By:**  
                 **Name:**  
                 **Title:**

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

APPENDIX A  
STATEMENT OF WORK  
TO BE ATTACHED

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

APPENDIX B  
QUALITY AGREEMENT

TO BE ATTACHED

**Exhibit J - Stock Purchase Agreement**

STOCK PURCHASE AGREEMENT

Dated as of [                      ]

Between  
Regenicin , Inc.  
["PURCHASER"]

And

Lonza Walkersville, Inc.  
["COMPANY"]  
with respect to all outstanding capital stock of  
the Cutanogen Corporation  
("Cutanogen")

## STOCK PURCHASE AGREEMENT

This STOCK PURCHASE AGREEMENT, dated as of [ ](this "Agreement"), is between Regenicin, Inc., a Nevada corporation ("Purchaser"), and Lonza Walkersville, Inc., a Delaware corporation (the "Company"). Certain terms used in this Agreement without definition shall have their meanings as defined in Section 8.11.

### WITNESSETH:

WHEREAS, the Company owns all of the issued and outstanding capital stock of Cutanogen (referred to herein as the "Cutanogen Shares");

WHEREAS, Cutanogen is engaged in the research and development of products used in the life sciences industry ("Cutanogen Business");

WHEREAS, the parties have entered into a Know-How License and Stock Purchase Agreement, dated June 30, 2009 (the "License and SPA");

WHEREAS, upon the occurrence of certain events delineated in the License and SPA, the Company desires to sell, and Purchaser desires to purchase, the Cutanogen Shares on the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the representations, warranties, covenants and agreements contained in this Agreement, and intending to be legally bound hereby, Purchaser and the Company hereby agree as follows:

### ARTICLE I

#### SALE OF SHARES AND CLOSING

SECTION 1.1 Purchase and Sale. The Company agrees to sell to Purchaser, and Purchaser agrees to purchase from the Company, all of the right, title and interest of the Company in and to the Cutanogen Shares at the Closing on the terms and subject to the conditions set forth in this Agreement.

(b) Company acknowledges receipt of two IDillion dollars (\$2,000,000) from Purchaser as the aggregate purchase price for the Cutanogen Shares in accordance with Paragraph 6.2 of the License and SPA, to which this Agreement is attached. The parties agree that (i) Company will retain the exclusive right to manufacture the PermaDerm product line at a customary margin level as more defInitively set forth in the form of agreement (" Manufacturing Agreement" ) attached hereto as Exhibit 1.2b and Purchaser will be responsible for gaining regulatory approval of PermaDerm and all associated expenses including those which Company might incur under the Manufacturing Agreement; and (ii) in addition, Company will retain the distribution rights for the collagen sponge, which is the tissue engineered matrix of PermaDerm. Under such distribution agreement Company will keep 15% of the collagen sponge sale price as a logistics/distribution fee. Additionally, any remaining profit from the sale of the sponge to a third party will be split equally between the parties. The distribution agreement will contain a list of those entities which will not be included as part of its distribution rights. Notwithstanding the above, in order to effectuate these rights to be retained by Company, Purchaser will provide Company with a worldwide, transferable, non-revocable license enabling Company to perform such tasks.

SECTION 1.2 Closing. The closing of the purchase and sale of the Cutanogen Shares pursuant to this Agreement (the " Closing" ) shall take place at 10:00 a.m. (New York time) on a date to be specified by the parties (the " Closing Date" ), which date shall be no later than the second (2<sup>nd</sup>) business day after the achievement of certain milestones included in the License and SPA and satisfaction or waiver of the conditions set forth in Article V (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of those conditions at such time), at the offices of Lonza Inc., 90 Boroline Road, Allendale, NJ 07401, unless another time, date or place is agreed to in writing by the parties hereto. At the Closing, the Company will assign and transfer to Purchaser all of Company's right, title and interest in and to the Cutanogen Shares by delivering to Purchaser certificates representing the Cutanogen Shares, in genuine and unaltered form, duly endorsed in blank or accompanied by duly executed stock powers endorsed in blank, with requisite stock transfer tax stamps, if any, attached. At the Closing, there shall also be delivered to the Company and Purchaser the certificates and other instruments to be delivered under Article V.

SECTION 1.3 Further Assurances: Post-Closing Cooperation.

(a) Subject to the terms and conditions of this Agreement, at any time or from

time to time after the Closing, each of the parties hereto shall execute and deliver such other documents and instruments, provide such materials and information and take such other actions as may reasonably be necessary, proper or advisable, to the extent permitted by Law, to fulfill its obligations under this Agreement.

(b) Following the Closing, each party will afford the other party, its counsel and

its accountants, during normal business hours, reasonable access to the books, records, personnel files, payroll files and other data relating to the Cutanogen Business in its possession with respect to periods prior to the Closing and the right to make copies and extracts therefrom, to the extent that such access may be reasonably required by the requesting party in connection with (i) the preparation of Tax Returns, (ii) the determination or enforcement of rights and obligations under this Agreement, (iii) compliance with the requirements of any Governmental Authority, (iv) in connection with any actual or threatened Action or Proceeding or (v) the determination of pension or other benefits. Further, each party agrees for a period extending six (6) years after the Closing Date not to destroy or otherwise dispose of any such books, records, personnel files, payroll files and other data unless such party shall frst offer in writing to surrender such books, records, personnel files, payroll files and other data to the other party and such other party shall not agree in writing to take possession thereof during the sixty (60) day period after such offer is made.

(c) If, in order properly to prepare its Tax Returns, other documents or reports required to be filed with Governmental Authorities or its financial statements or to fulfill its obligations hereunder, it is necessary that a party be furnished with additional information, documents or records relating to the Cutanogen Business not referred to in paragraph (b) above, and such information, documents or records are in possession or control of the other party, such other party agrees to use its reasonable best efforts to furnish or make available such information, documents or records (or copies thereof) at the recipient's request, cost and expense.

(d) Notwithstanding anything to the contrary contained in this Section, if the parties are in an adversarial relationship in litigation or arbitration, the furnishing of information, documents or records in accordance with any provision of this Section 1.4 shall be subject to applicable rules relating to discovery.

## ARTICLE II

### REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to Purchaser that:

#### SECTION 2.1 Organization and Standing .

(a) Company is a corporation or other organization validly existing and in good standing under the Laws of its jurisdiction of incorporation or organization. Company is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned or leased or held under license by it makes such licensing or qualification necessary, except where the failure to be so licensed, qualified or in good standing would not, individually or in the aggregate, reasonably be expected to impair in any material respect the ability of Company to perform its obligations hereunder or prevent or materially delay consummation of the Cutanogen Transaction.

(b) Cutanogen is a corporation or other organization validly existing and in good standing under the Laws of the jurisdiction of its incorporation or organization.



SECTION 2.2

Capitalization. (a) All the outstanding shares of capital stock of, or other equity interests in, Cutanogen are duly authorized, have been validly issued, are fully paid, nonassessable and free of preemptive rights, and are owned directly by Company free and clear of all liens, pledges, security interests and transfer restrictions, except for such transfer restrictions of general applicability as may be provided under applicable securities Laws and rules and regulations promulgated thereunder (" Liens "). The delivery of certificates at the Closing representing the Cutanogen Shares in the manner provided in Section 1.3 will transfer to Purchaser good and valid title to the Cutanogen Shares, free and clear of all Liens other than Liens created or suffered to exist by Purchaser.

(b) There are no outstanding contractual obligations of the Company or any of its Subsidiaries (i) restricting the transfer of, (ii) affecting the voting rights of, (iii) requiring the sale, issuance or other disposition of, or the repurchase, redemption or disposition of, or containing any right of first refusal with respect to, (iv) requiring the registration for sale of, or (v) granting any preemptive or anti-dilutive right with respect to, any shares of capital stock of, or other equity interests in, Cutanogen.

SECTION 2.3

Authority; Noncontravention; Voting Requirements.

(a) The Company has all necessary corporate power and authority to execute and deliver this Agreement and, subject to obtaining the Company Stockholder Authorization, to perform its obligations hereunder and to consummate the Cutanogen Transaction. The execution, delivery and performance by the Company of this Agreement, has been duly authorized and approved by the board of directors of Company, and except for obtaining the Company Stockholder Authorization, no other corporate action on the part of any of Company is necessary to authorize the execution, delivery and performance by the Company of this Agreement. This Agreement has been duly executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by Purchaser, constitutes a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except that such enforceability (i) may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other similar Laws of general application affecting or relating to the enforcement of creditors' rights generally and (ii) is subject to general principles of equity, whether considered in a proceeding at Law or in equity (the " Bankruptcy and Equity Exception ").

(b) The Company Board, at a meeting duly called and held, has or will have (i) approved and declared advisable this Agreement and directed that this Agreement be submitted to the holders of shares of Company Common Stock for their authorization.

(c) The execution and delivery of this Agreement by the Company, will not (i) conflict with or violate any provision of the certificate of incorporation or bylaws (or other comparable organization documents) or (ii) assuming that the authorizations, consents and approvals referred to in Section 2.4 and the Company Stockholder Authorization are obtained and the filings referred to in Section 2.4 are made, (x) violate any Law, judgment, writ or injunction of any Governmental Authority applicable to the Company or any of its Subsidiaries or (y) violate or constitute a default under any of the terms, conditions or provisions of any loan or credit agreement, debenture, note, bond, mortgage, indenture, deed of trust, lease, contract or other agreement (each, a " Contract ") to which the Company or any of its Subsidiaries is a party, except, in the case of clause (ii), for such violations or defaults as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect or to impair in any material respect the ability of Company to perform its obligations hereunder.

SECTION 2.4 Governmental Approvals . Except for (i) a possible filing with the Swiss Stock Exchange ("SWX"), (ii) filings required under, and compliance with other applicable requirements of, the HSR Act and (iii) filings required under, and compliance with other applicable requirements of, non-U.S. Laws intended to prohibit, restrict or regulate actions or transactions having the purpose or effect of monopolization, restraint of trade, harm to competition or effectuating foreign investment (collectively, "Foreign Antitrust Laws"), no consents or approvals of, or filings, declarations or registrations with, any Governmental Authority are necessary for the execution and delivery of this Agreement by the Company, other than such consents, approvals, filings, declarations or registrations that, if not obtained, made or given, would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect or to impair in any material respect the ability of the Company to perform its obligations hereunder.

SECTION 2.5 Intellectual Property .  
(a) As used herein: (i) "Intellectual Property" means all U.S. and foreign (A) trademarks, service marks, trade names, Internet domain names, designs, logos and slogans, together with goodwill, registrations and applications relating to the foregoing ("Trademarks"), (B) patents and pending patent applications, invention disclosure statements, and any and all divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof, any counterparts claiming priority therefrom and like statutory rights ("Patents"), (C) registered and unregistered copyrights (including those in Software) and registrations and applications to register the same ("Copyrights"), (D) confidential technology, know-how, inventions, processes, formulae, algorithms, models and methodologies ("Trade Secrets") and (E) databases and compilations, including any and all electronic data and electronic collections of data; (ii) "IP Licenses" means any license or sublicense rights in or to any Intellectual Property; and (iii) "Software" means all computer programs, including any and all software implementations of algorithms, models and methodologies whether in source code or object code form, and all documentation, including user manuals and training materials, related to any of the foregoing. A list of any Intellectual Property is attached hereto as Exhibit 2.5a.

(b) Except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, Cutanogen owns or possesses appropriate licenses or other legal rights to use, sell or license all Cutanogen Intellectual Property.

(c) Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, all Trademark registrations and applications for registration, Patents issued or pending and Copyright registrations and applications for registration included in the Cutanogen Intellectual Property are valid and subsisting, in full force and effect and have not lapsed, expired or been abandoned (subject to the vulnerability of a registration for Trademarks to cancellation for lack of use), and, to the Knowledge of the Company, are not the subject of any opposition filed with the United States Patent and Trademark Office or any other Intellectual Property registry.

(d) to the Knowledge of the Company, the conduct of the Cutanogen Business does not infringe, misappropriate, or otherwise violate any Intellectual Property rights of any third party.

(e) to the Knowledge of the Company, no third party IS infringing, misappropriating, diluting or violating any Cutanogen Intellectual Property.

SECTION 2.6 Brokers and Other Advisors. No broker, investment banker,

financial advisor or other Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission, or the reimbursement of expenses, in connection with the transaction contemplated herein.

SECTION 2.7 No Other Representations or Warranties. Except for the

representations and warranties made by the Company in this Article II or pursuant to the certificates to be delivered pursuant to Section 5.2(a), neither the Company nor any other Person makes any representation or warranty with respect to Cutanogen or, notwithstanding the delivery or disclosure to Purchaser or any of its Affiliates or representatives of any documentation, forecasts or other information with respect to anyone or more of the foregoing.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to the Company that:

SECTION 3.1 Organization and Standing. Purchaser is a corporation validly existing and in good standing under the Laws of the State of Nevada. Purchaser is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned or leased or held under license by it makes such licensing or qualification necessary, except where the failure to be so licensed, qualified or in good standing would not, individually or in the aggregate, reasonably be expected to impair in any material respect the ability of Purchaser to perform its obligations hereunder or prevent or materially delay consummation of the Transaction.

SECTION 3.2 Authority; Noncontravention.

(a) Purchaser has all necessary corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the Transaction. The execution, delivery and performance by Purchaser of this Agreement, and the consummation by Purchaser of the Transaction, have been duly authorized and approved by its board of directors, and no other corporate action on the part of Purchaser is necessary to authorize the execution, delivery and performance by Purchaser of this Agreement and the consummation by it of the Transaction. This Agreement has been duly executed and delivered by Purchaser and, assuming due authorization, execution and delivery hereof by the Company, constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject to the Bankruptcy and Equity Exception.

(b) Neither the execution and delivery of this Agreement by Purchaser, nor the consummation by Purchaser of the Transaction, nor compliance by Purchaser with any of the terms or provisions hereof, will (i) conflict with or violate any provision of the certificate of incorporation or bylaws of Purchaser or (ii) assuming that the authorizations, consents and approvals referred to in Section 3.3 are obtained and the filings referred to in Section 3.3 are made, (x) violate any Law, judgment, writ or injunction of any Governmental Authority applicable to Purchaser or any of its Subsidiaries, or (y) violate or constitute a default under any of the terms, conditions or provisions of any Contract to which Purchaser or any of its Subsidiaries is a party, except, in the case of clause (ii), for such violations or defaults as would not, individually or in the aggregate, reasonably be expected to impair the ability of Purchaser to perform its obligations hereunder or prevent or materially delay consummation of the Transaction.

(c) No vote of the holders of any class or series of Purchaser's capital stock or other securities is necessary for the consummation by Purchaser of the Transaction.

**SECTION 3.3** Governmental Approvals. No consents or approvals of, or filings, declarations or registrations with, any Governmental Authority are necessary for the .. execution, delivery and performance of this Agreement by Purchaser, other than such other consents, approvals, filings, declarations or registrations that, if not obtained, made or given, would not, individually or in the aggregate, reasonably be expected to impair in any material respect the ability of Purchaser to perform its obligations hereunder or prevent or materially delay consummation of the Transaction.

**SECTION 3.4** Information Supplied. Any information supplied by Purchaser to Company will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein.

**SECTION 3.5** Capital Resources. Purchaser has, or will have prior to the Closing, cash, available lines of credit or other sources of immediately available funds in an amount sufficient to pay all fees and expenses payable by Purchaser. To the extent that Purchaser is financing all or a portion of the Transaction through proceeds received from debt financing provided by third parties, prior to the execution and delivery of this Agreement Purchaser has furnished to the Company fully executed copies of the debt commitment letters relating to such financing with conditions precedent no more restrictive than the conditions to Closing contained in this Agreement. As of the date hereof and after communicating with the institutions providing such debt financing, Purchaser knows of no facts or circumstances (other than any that arise as a result of a breach by the Company of this Agreement) that are reasonably likely to result in any of the conditions set forth in such commitment letters not being satisfied.

**SECTION 3.6** Legal Proceedings. As of the date hereof, there is no pending or, to the Knowledge of Purchaser, threatened Action or Proceeding against or relating to Purchaser or any of its Subsidiaries, nor is there any injunction, order, judgment, ruling or decree imposed upon Purchaser or any of its Subsidiaries, in each case, by or before any Governmental Authority, that would, individually or in the aggregate, reasonably be expected to impair in any material respect the ability of Purchaser to perform its obligations hereunder.

SECTION 3.7 Brokers and Other Advisors . No broker, investment banker, financial advisor or other Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission, or the reimbursement of expenses, in connection with the Transaction based upon arrangements made by or on behalf of Purchaser or any of its Subsidiaries.

SECTION 3.8 No Reliance. Notwithstanding anything contained in this Agreement to the contrary, Purchaser acknowledges and agrees that (a) neither the Company nor any Person on behalf of the Company is making any representations or warranties whatsoever, express or implied, beyond those expressly made by the Company in Article II, and (b) Purchaser has not been induced by, or relied upon, any representations, warranties or statements (written or oral), whether express or implied, made by any Person, that are not expressly set forth in Article II of this Agreement. Without limiting the generality of the foregoing, Purchaser acknowledges that no representations or warranties are made with respect to any projections, forecasts, estimates, budgets or information as to prospects with respect to the Cutanogen Business that may have been made available to Purchaser or any of its representatives.

#### ARTICLE IV

#### ADDITIONAL COVENANTS AND AGREEMENTS

SECTION 4.1 Reasonable Best Efforts .

(a) Subject to the terms and conditions of this Agreement, each of the Company and Purchaser shall cooperate with the other and use (and shall cause their respective Subsidiaries to use) their respective reasonable best efforts, to the fullest extent permitted by applicable Law, to promptly (i) take, or cause to be taken, all actions, and do, or cause to be done, all things, necessary, proper or advisable to cause the conditions to Closing to be satisfied as promptly as practicable and to consummate and make effective, in the most expeditious manner practicable, the Transaction, including preparing and filing promptly and fully all documentation to effect all necessary filings, notices, petitions, statements, registrations, submissions of information, applications and other documents (including any required or recommended filings under applicable Antitrust Laws), and (ii) obtain all approvals, consents, registrations, permits, authorizations and other confirmations from any Governmental Authority or third party necessary, proper or advisable to consummate the Transaction. For purposes hereof, "Antitrust Laws" means the Sherman Act, as amended, the Clayton Act, as amended, the HSR Act, the Federal Trade Commission Act, as amended, all applicable Foreign Antitrust Laws and all other applicable Laws issued by a Governmental Authority that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening of competition through merger or acquisition.

(b) Each of the Company and Purchaser shall use its reasonable best efforts to (i) cooperate in all respects with each other in connection with any filing or submission with a Governmental Authority in connection with the Transaction and in connection with any investigation or other inquiry by or before a Governmental Authority relating to the Transaction, including any proceeding initiated by a private party, and (ii) keep the other party informed in all material respects and on a reasonably timely basis of any material communication received by such party from, or given by such party to, the Federal Trade Commission, the Antitrust Division of the Department of Justice, or any other Governmental Authority and of any material communication received or given in connection with any proceeding by a private party, in each case regarding the Transaction. Subject to applicable Laws relating to the exchange of information, each of the parties hereto shall have the right to review in advance, and to the extent practicable each will consult the other on, all the information relating to the other party and its Subsidiaries, as the case may be, that appears in any filing made with, or written materials submitted to, any third party and/or any Governmental Authority in connection with the Transaction.

(c) In furtherance and not in limitation of the covenants of the parties contained in this Section 4.5, each of the Company and Purchaser shall use its reasonable best efforts to resolve such objections, if any, as may be asserted by a Governmental Authority or other Person with respect to the Transaction. Without limiting any other provision hereof, Purchaser and the Company shall each use its reasonable best efforts to (i) avoid the entry of, or to have vacated or terminated, any decree, order or judgment that would restrain, prevent or delay the consummation of the Transaction, including by defending through litigation on the merits any claim asserted in any court by any Person, and (ii) avoid or eliminate each and every impediment under any Antitrust Law that may be asserted by any Governmental Authority with respect to the Transaction so as to enable the consummation of the Transaction to occur as soon as reasonably possible including, in the case of Purchaser, by taking all such actions, including (x) proposing, negotiating, committing to and effecting, by consent decree, hold separate order, or otherwise, the sale, divestiture or disposition of such assets or businesses of Purchaser (or any of its Subsidiaries) and (y) otherwise taking or committing to take actions that limit Purchaser or its Subsidiaries' freedom of action with respect to, or its ability to retain, one or more of its, or its Subsidiaries', businesses, product lines or assets, in each case, as may be required in order to avoid the entry of, or to effect the dissolution of, any injunction, temporary restraining order or other order in any Action or Proceeding, which would otherwise have the effect of preventing or materially delaying the consummation of the Transaction.

**SECTION 4.2** Public Announcements. The initial press release with respect to the execution of this Agreement shall be a joint press release to be reasonably agreed upon by Purchaser and the Company. Thereafter, neither the Company nor Purchaser shall issue or cause the publication of any press release or other public announcement (to the extent not previously issued or made in accordance with this Agreement) with respect to this Agreement or the Transaction without the prior consent of the other party (which consent shall not be unreasonably withheld, conditioned or delayed), except as may be required by Law, applicable fiduciary duties or by any applicable listing agreement with the SW:X as determined in the good faith judgment of the party proposing to make such release (in which case such party shall not issue or cause the publication of such press release or other public announcement without prior consultation with the other party to the extent reasonably practicable).

SECTION 4.3 Access to Information; Confidentiality. Subject to applicable Laws relating to the exchange of information, the Company shall afford to Purchaser reasonable access during normal business hours to the officers, employees, accountants, properties, books, Contracts and records of the Company relating to the Cutanogen Business, and the Company shall furnish promptly to Purchaser other information concerning the Cutanogen Business as Purchaser may reasonably request; provided, however, that the Company shall not be obligated to provide such access or information if the Company determines, in its reasonable judgment, that doing so would violate applicable Law or a Contract or obligation of confidentiality owing to a third party or jeopardize the protection of an attorney-client privilege. Until the Closing Date, the information provided pursuant to this Agreement will be subject to the terms of the Confidentiality Agreement, dated as of [J], between Purchaser and the Company (as it may be amended from time to time, the "Confidentiality Agreement"), which shall survive the termination of this Agreement in accordance with the terms of the Confidentiality Agreement.

SECTION 4.4 Notification of Certain Matters. The Company shall give prompt notice to Purchaser, and Purchaser shall give prompt notice to the Company, of (i) any notice or other communication received by such party from any Governmental Authority in connection with the Transaction or from any Person alleging that the consent of such Person is or may be required in connection with the Transaction, and (ii) any Actions or Proceedings commenced or, to such party's Knowledge, threatened against, relating to or involving or otherwise affecting such party or any of its Subsidiaries which, in the case of either clause (i) or (ii), would reasonably be expected to have a Material Adverse Effect or prevent or materially delay consummation of the Transaction.

SECTION 4.5 Fees and Expenses. Except as provided in Section 7.3, all fees and expenses incurred in connection with this Agreement and the Transaction shall be paid by the party incurring such fees or expenses, whether or not the Transaction are consummated.

## ARTICLE V

### CONDITIONS

SECTION 5.1 Conditions to the Obligations of Each Party. The respective obligations of each party hereto to consummate the Transaction shall be subject to the satisfaction (or waiver, if permissible under applicable Law) on or prior to the Closing Date of the following conditions:

- (a) The Company Stockholder Authorization shall have been obtained.
- (b) No Law, injunction, judgment or ruling enacted, promulgated, issued, entered, amended or enforced by any Governmental Authority (collectively, the "Restraints") shall be in effect enjoining, restraining, preventing or prohibiting consummation of the Transaction or making the consummation of the Transaction illegal.

(c) All consents, approvals and actions of, filings with and notices to any Governmental Authority required of Purchaser, the Company or any of their respective Subsidiaries to consummate the Transaction, the failure of which to be obtained or taken would be reasonably expected to have a Material Adverse Effect or an adverse effect on the ability of Purchaser and the Company to consummate the Transaction, shall have been obtained; provided that no such consent, approval, action, filing or notice under the Foreign Antitrust Laws shall be a condition to either party's obligations to consummate the Transaction. Without limiting the foregoing, any applicable waiting period under the HSR Act (and any extension thereof) shall have expired or terminated.

(d) The Purchaser shall have delivered a fully executed original copy of each of (i) the Consulting Agreement ("Consulting Agreement") dated February 2, 2006 between Steven T. Boyce and Cambrex BioScience Walkersville, Inc. and (ii) the Stock Purchase Agreement ("SPA") dated February 2, 2006 between certain Sellers and Cambrex BioScience Walkersville, Inc. regarding the sale of Cutanogen reflecting an assignment of both Agreements to Purchaser. Additionally, the SPA shall be revised so that such assignment allows Company to have no liability under said SPA.

(e) The achievement of certain milestones included in the License and SP A.

SECTION 5.2 Conditions to the Obligations of Purchaser. The obligations of Purchaser to consummate the Transaction shall be subject to the satisfaction (or waiver, if permissible under applicable Law) on or prior to the Closing Date of the following conditions:

(a) Each of the representations and warranties of the Company set forth in this Agreement shall be true and correct at and as of the Closing Date as if made on such date (other than those representations and warranties that address matters only as of a particular date, which shall be true and correct as of such date), except (x) for changes permitted by this Agreement or (y) where the failure of any such representation or warranty to be true and correct (without giving effect to any limitation as to "materiality" or "Material Adverse Effect" set forth therein) would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and Purchaser shall have received a certificate of an executive officer of the Company to that effect.

(b) The Company shall have performed or complied with in all material respects all agreements and covenants required by this Agreement to be performed or complied with by it on or prior to the Closing Date; and Purchaser shall have received a certificate of an executive officer of the Company to that effect.



SECTION 5.3 Conditions to the Obligations of the Company. The obligations of the Company to consummate the Transaction shall be subject to the satisfaction (or waiver, if permissible under applicable Law) on or prior to the Closing Date of the following conditions:

(a) Each of the representations and warranties of Purchaser set forth in this Agreement shall be true and correct at and as of the Closing Date as if made on such date, except where the failure of any such representation or warranty to be true and correct would not, individually or in the aggregate, reasonably be expected to impair the ability of Purchaser to perform its obligations hereunder or prevent or materially delay consummation of the Transaction; and the Company shall have received a certificate of an executive officer of Purchaser to that effect.

(b) Purchaser shall have performed or complied with in all material respects all agreements and covenants required by this Agreement to be performed or complied with by it on or prior to the Closing Date; and the Company shall have received a certificate of an executive officer of Purchaser to that effect.

SECTION 5.4 Frustration of Closing Conditions. Neither the Company nor Purchaser may rely on the failure of any condition set forth in Section 5.1, 5.2 or 5.3, as the case may be, to be satisfied if such failure was caused by such party's failure to use reasonable best efforts to consummate the Transaction, to the extent required by and subject to Section 4.4 and the other applicable provisions of Article IV.

## ARTICLE VI

### TAX MATTERS

SECTION 6.1 Tax Filings.

(a) After the Closing, Purchaser shall prepare and file, or cause to be prepared and filed, on behalf of Cutanogen all Cutanogen Tax Returns (if necessary), and pay (or cause to be paid) all Taxes shown due on such Tax Returns.

(b) To the extent permitted by applicable Law or administrative practice of any Taxing Authority, any transactions involving Cutanogen that are not in the ordinary course of business occurring on the Closing Date but after the Closing shall be reported on Purchaser's consolidated United States federal income Tax Return to the extent permitted by Treasury Regulation § 1.1502-76(b)(1)(ii)(B).

(c) Purchaser and the Company agree to furnish or cause to be furnished to each other, and each at its own expense, as promptly as practicable, such information (including access to books and records) and assistance, including making employees available on a mutually convenient basis to provide additional information and explanations of any material provided relating to Cutanogen, as is reasonably necessary for the filing of any Tax Returns, for the preparation for any audit and for the prosecution or defense of any Action or Proceeding relating to any adjustment or proposed adjustment with respect to Taxes. Purchaser shall retain in its possession, and shall provide the Company reasonable access to (including the right to make copies of), such supporting books and records and any other materials that the Company may specify with respect to matters relating to Taxes for any taxable period ending on or prior to or which includes the Closing Date until the relevant statute of limitations has expired. After such time, Purchaser may dispose of such material; provided, that prior to such disposition Purchaser shall give the Company a reasonable opportunity at its expense to take possession of such materials.

(d) Neither Purchaser nor any Affiliate or successor of Purchaser shall amend, refile or otherwise modify any Tax Return relating in whole or in part to Cutanogen with respect to any taxable year or period ending on or before December 31, 2007, without the prior written consent of the Company.

**SECTION 6.2** Certain Other Taxes. All transfer, documentary, sales, use, stamp, registration and other such Taxes and fees (including any penalties and interest) incurred in connection with this Agreement, if any, shall be paid 50% by Purchaser and 50% by the Company, and the party obligated under applicable Law to file all necessary Tax Returns and other documentation with respect to any such transfer, documentary, sales, use, stamp, registration and other Taxes and fees, shall file such Tax Returns or other documentation and, if required by applicable Law, the other party will, and will cause its Affiliates to, join in the execution of any such Tax Returns and other documentation and will cooperate with the other party to take such commercially reasonable actions as will minimize or reduce the amount of such Taxes or fees.

**SECTION 6.3** Tax Audits.

(a) The Company shall have the sole right (but not the obligation) to represent the interests of Cutanogen in any audit or administrative or court proceeding relating to (i) Taxes described in Section 6.1(a) and (ii) with respect to all other Taxes, Taxes for taxable periods ending on or before December 31, 2007 and, in each case, the Company shall have the right to employ counsel of its choice at its expense.

(b) Purchaser shall have the sole right to represent the interests of Cutanogen in all other audits or administrative or court proceedings relating to Taxes.

(c) The Company, on the one hand, and Purchaser, on the other hand, shall not enter into any compromise or agree to settle any claim pursuant to any Tax audit or proceeding which would adversely affect the other party without the written consent of the other party.

#### SECTION 6.4 Indemnification.

After the Closing Date, Purchaser shall, to the fullest extent permitted by applicable Law, indemnify and hold harmless the Company and its Affiliates from and against any and all Tax Losses arising out of or relating to any Taxes of Cutanogen.

SECTION 6.5 Refunds. Any refunds of Taxes (together with any interest with respect thereto) paid to or in respect of Cutanogen (including any amounts credited against income Tax to which Purchaser, its Affiliates) and that relate to Taxes for which the Company is responsible pursuant to this Article VI shall be for the account of the Company. Purchaser shall pay over to the Company any such refund or the amount of any such credit (in each case, together with any interest with respect thereto) within fifteen (15) days after receipt or entitlement thereto. Purchaser shall, if the Company so requests and at the Company's expense, prepare, execute and file any claims for refunds or credits, to which the Company is entitled under this Section. Purchaser shall permit the Company to control the prosecution of any such refund.

#### SECTION 6.6 Certain Elections and Other Tax Matters

(a) At the Company's request, Purchaser shall make or join in making any elections under Section 338 of the Code (and any comparable election under any relevant state or local Law) (a " Section 338 Election ") with respect to the purchase and sale of the Cutanogen Shares. In no event shall Purchaser make a Section 338 Election with respect to Cutanogen without the prior written consent of the Company. If the Company shall decide to make one or more Section 338 Elections, it shall notify Purchaser in writing of such decision within sixty (60) days after the Closing Date. If, pursuant to this Section, the Company determines to make a Section 338 Election, the Company shall propose an allocation of the applicable Purchase Price (which, for this purpose, shall include any liabilities properly taken into account for purposes of determining the purchase price under Code Section 338) in accordance with Code Section 1060 and the Treasury Regulations promulgated thereunder (and any similar provision of state, local or foreign Law, as appropriate), and shall notify Purchaser in writing of such proposed Purchase Price allocation within thirty (30) days following delivery of the notification of the Company's decision to make a Section 338 Election. The parties shall cooperate in good faith to agree on an allocation of the Purchase Price and, once agreed to, the allocation shall be binding on the parties (the " Allocation "). Additionally, the parties agree to share equally the total benefit received or achieved by the parties as a result of such Section 338 Election. If the parties cannot agree upon the Allocation within thirty (30) days following the Company's delivery of its proposed allocation to Purchaser, the parties shall submit any disputes to three (3) Independent Accountants. The Independent Accountants shall finally and conclusively resolve any disputed matters in accordance with Code Section 1060 within thirty (30) days following receipt of the submission. Purchaser and the Company shall report and file Tax Returns (including but not limited to Internal Revenue Service Form 8594) in all respects and for all purposes consistent with the Allocation. Neither Purchaser nor the Company shall take any position (whether in audits, Tax Returns or otherwise) that is inconsistent with the Allocation unless required to do so by applicable Law. Within 180 days following the Closing, the Company shall deliver to Purchaser IRS Form 8023 (or applicable successor form) for which a Section 338 Election is made, fully executed by the Company or other applicable sellers pursuant to the requirements stated therein.

(b) It is the intention of the parties to treat any indemnity payment made under this Article VI as an adjustment to the Purchase Price for all federal, state, local and foreign Tax purposes, and the parties agree to file their Tax Returns accordingly.

(c) At least five (5) business days prior to the Closing, the Company shall deliver to Purchaser a schedule setting forth the allocation of the Purchase Price, which allocation shall be binding on the parties.

## ARTICLE

### INDEMNIFICATION

**SECTION 7.1** Indemnification by the Company. Following the Closing, except with respect to Taxes (which shall be governed exclusively by Article V D), the Company shall, to the fullest extent permitted by applicable Law, indemnify, defend and hold harmless Purchaser, each Affiliate of Purchaser and each of their respective directors, officers, successors and assigns (the "Purchaser Indemnitees") from and against any and all Losses suffered or incurred by any of the Purchaser Indemnitees arising out of or resulting from the breach of any representation or warranty made by Company in Article IT of this Agreement. All such representations and warranties will survive the Closing and remain in full force and effect for a period of ninety (90) days following the Closing Date.

**SECTION 7.2** Indemnification by Purchaser. Following the Closing, except with respect to Taxes (which shall be governed exclusively by Article YD), Purchaser shall, to the fullest extent permitted by applicable Law, indemnify, defend and hold harmless the Company, each Affiliate of the Company and each of their respective directors, officers, employees, successors and assigns (the "Company Indemnitees") from and against any and all Losses suffered or incurred by any of the Company Indemnitees arising out of or resulting from any Cutanogen Liability (including, with()11.tJJrnit~ti2P.,~~iJ:lg out of the failure of Purchaser or Cutanogen to pay, perform or otherwise discharge when due any such Cutanogen Liability), whether arising prior to, on or after the Closing. This indemnity shall also apply in the event of the Purchaser's breach of any representation or warranty that it has made in Article ill of this Agreement. All such representations and warranties will survive the Closing and remain in full force and effect for a period of ninety (90) days following the Closing Date.

**SECTION 7.3** Limitations on Indemnification Obligations. The amount which any party (an "Indemnifying Party") is or may be required to pay to any other party (an "Indemnitee") pursuant to Section 7.1 or Section 7.2 shall be reduced (including, without limitation, retroactively) by any Insurance Proceeds or other amount actually recovered by or on behalf of such Indemnitee, in reduction of the related Loss. If an Indemnitee shall have received the payment required by this Agreement from an Indemnifying Party in respect of any Loss and shall subsequently actually receive Insurance Proceeds or other amounts in respect of such Loss, then such Indemnitee shall pay to such Indemnifying Party a sum equal to the amount of such Insurance Proceeds or other amounts actually received (up to but not in excess of the amount of any indemnity payment made hereunder). An insurer who would otherwise be obligated to pay any claim shall not be relieved of the responsibility with respect thereto, or, solely by virtue of the indemnification provisions hereof, have any subrogation rights with respect thereto, it being expressly understood and agreed that no insurer or any other third party shall be entitled to a "windfall" (i.e., a benefit they would not be entitled to receive in the absence of the indemnification provisions) by virtue of the indemnification provisions hereof.

SECTION 7.4

Procedures for Indemnification of Third Party Claims . Procedures for indemnification of

Third Party Claims shall be as follows:

(a) If an Indemnitee shall receive notice or otherwise learn of the assertion by a Person (including, without limitation, any Governmental Authority) who is not a party to this Agreement of any claim or of the commencement by any such Person of any Action or Proceeding (a " Third Party Claim ") with respect to which an Indemnifying Party may be obligated to provide indemnification pursuant to Section 7.1 or Section 7.2 , such Indemnitee shall give such Indemnifying Party written notice thereof promptly after becoming aware of such Third Party Claim; provided that the failure of any Indemnitee to give notice as provided in this Section 7.4(a) shall not relieve the related Indemnifying Party of its obligations under this Article VII , except to the extent that such Indemnifying Party is prejudiced by such failure to give notice. Such notice shall describe the Third Party Claim in reasonable detail and, if ascertainable, shall indicate the amount (estimated if necessary) of the Loss that has been or may be sustained by such Indemnitee.

(b) An Indemnifying Party may elect to defend or to seek to settle or compromise, at such Indemnifying Party's own expense and by such Indemnifying Party's own counsel, any Third Party Claim. Within thirty (30) days after the receipt of notice from an Indemnitee in accordance with Section 704(a) (or sooner, if the nature of such Third Party Claim so requires), the Indemnifying Party shall notify the Indemnitee whether the Indemnifying Party will assume responsibility for defending such Third Party Claim. After notice from an Indemnifying Party to an Indemnitee of its election to assume the defense of a Third Party Claim, such Indemnifying Party shall not be liable to such Indemnitee under this Article vn for any legal or other expenses ( except expenses approved in advance by the Indemnifying Party) subsequently incurred by such Indemnitee in connection with the defense thereof; provided that if the defendants in any such claim include both the Indemnifying Party and one or more Indemnitees and in any Indemnitee's reasonable judgment a conflict of interest between one or more of such Indemnitees and such Indemnifying Party exists in respect of such claim, such Indemnitees shall have the right to employ separate counsel to represent such Indemnitees and in that event the reasonable fees and expenses of such separate counsel (but not more than one separate counsel reasonably satisfactory to the Indemnifying Party) shall be paid by such Indemnifying Party. If an Indemnifying Party elects not to assume responsibility for defending a Third Party Claim, or fails to notify an Indemnitee of its election as provided in this Section 704(b) , such Indemnitee may defend or (subject to the remainder of this Section 704(b) and Section 704(d) .) seek to compromise or settle such Third Party Claim at the expense of the Indemnifying Party. Neither an Indemnifying Party nor an Indemnitee shall consent to entry of any judgment or enter into any settlement of any Third Party Claim which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnitee, in the case of a consent or settlement by an Indemnifying Party, or the Indemnifying Party, in the case of a consent or settlement by the Indemnitee, of a written release from all Liability in respect to such Third Party Claim.

(c) If an Indemnifying Party chooses to defend or to seek to compromise or settle any Third Party Claim, the related Indemnatee shall make available to such Indemnifying Party any personnel or any books, records or other documents within its control or which it otherwise has the ability to make available that are necessary or appropriate for such defense, settlement or compromise, and shall otherwise cooperate in the defense, settlement or compromise of such Third Party Claim.

(d) . Notwithstanding anything in this Section 704 to the contrary, neither an Indemnifying Party nor an Indemnatee may settle or compromise any claim over the objection of the other; provided, however, that consent to settlement or compromise shall not be unreasonably withheld, conditioned or delayed. If an Indemnifying Party notifies the related Indemnatee in writing of such Indemnifying Party's desire to settle or compromise a Third Party Claim on the basis set forth in such notice (provided that such settlement or compromise includes as an unconditional term thereof the giving by the claimant or plaintiff of a written release of the Indemnatee from all Liability in respect thereof) and the Indemnatee shall notify the Indemnifying Party in writing that such Indemnatee declines to accept any such settlement or compromise, such Indemnatee may continue to contest such Third Party Claim, free of any participation by such Indemnifying Party, at such Indemnatee's sole expense. In such event, the obligation of such Indemnifying Party to such Indemnatee with respect to such Third Party Claim shall be equal to (i) the costs and expenses of such Indemnatee prior to the date such Indemnifying Party notifies such Indemnatee of the offer to settle or compromise (to the extent such costs and expenses are otherwise indemnifiable hereunder) plus (ii) the lesser of (x) the amount of any offer of settlement or compromise which such Indemnatee declined to accept and (y) the actual out-of-pocket amount such Indemnatee is obligated to pay subsequent to such date as a result of such Indemnatee's continuing to pursue such Third Party Claim.

(e) In the event of payment by an Indemnifying Party to any Indemnatee in connection with any Third Party Claim, such Indemnifying Party shall, to the fullest extent permitted by applicable Law, be subrogated to and shall stand in the place of such Indemnatee as to any events or circumstances in respect of which such Indemnatee may have any right or claim relating to such Third Party Claim against any claimant or plaintiff asserting such Third Party Claim or against any other Person. Such Indemnatee shall cooperate with such Indemnifying Party in a reasonable manner, and at the cost and expense of such Indemnifying Party, in prosecuting any subrogated right or claim.

#### SECTION 7.5 Other Procedures for Indemnification.

(a) Any claim on account of a Loss which does not result from a Third Party Claim shall be asserted by written notice given by the Indemnatee to the related Indemnifying Party. Such Indemnifying Party shall have a period of thirty (30) days after the receipt of such notice within which to respond thereto. If such Indemnifying Party does not respond within such thirty (30) day period, such Indemnifying Party shall be deemed to have refused to accept responsibility to make payment. If such Indemnifying Party does not respond within such thirty (30) day period or rejects such claim in whole or in part, such Indemnatee shall be free to pursue such remedies as may be available to such party under this Agreement or under applicable Law.

(b) In addition to any adjustments required pursuant to Section 7.3, if the amount of any Loss shall, at any time subsequent to the payment required by this Agreement, be reduced by recovery, settlement or otherwise, the amount of such reduction, less any expenses incurred in connection therewith, shall promptly be repaid by the Indemnitee to the Indemnifying Party.

SECTION 7.6 Remedies Cumulative. The remedies provided in this Article VII shall be cumulative and shall not preclude assertion by an Indemnitee of any other rights or the seeking any and all other remedies against any Indemnifying Party.

SECTION 7.7 Survival of Indemnities. The obligations of each of the parties under this Article VII shall survive the sale or other transfer by it of any assets or businesses or the assignment by it of any Liabilities with respect to any Loss of the other related to such assets, businesses or Liabilities.

SECTION 7.8 Limitation of Liability. In no event shall an Indemnifying Party be liable under this Article VII for any special, consequential, indirect, incidental or punitive damages or lost profits, however caused and on any theory of Liability (including, without limitation, negligence) arising in any way out of this Article VII, whether or not such party has been advised of the possibility of such damages; provided, however, that the foregoing limitations shall not limit each party's indemnification obligations for Liabilities to third parties as set forth in this Article VII.

## ARTICLE VIII

### MISCELLANEOUS

SECTION 8.1 Survival of Representations, Warranties and Agreements. The representations and warranties contained herein or in any other writing delivered pursuant hereto, as well as any covenant or agreement of the parties that by its terms contemplates performance exclusively prior to the Closing Date, shall survive until (but not beyond) the Closing Date. Nothing in this paragraph shall limit any covenant or agreement of the parties that by its terms contemplates performance in whole or in part after the Closing Date.

SECTION 8.2 Amendment or Supplement. At anytime prior to the Closing Date, this Agreement may be amended or supplemented in any and all respects, whether before or after authorization of the Transaction by the holders of Company Common Stock, by written agreement of the parties hereto, by action taken by their respective boards of directors; provided, however, that following the Company Stockholder Authorization, there shall be no amendment or change to the provisions hereof which by Law or in accordance with the rules of any relevant stock exchange would require further approval by the holders of Company Common Stock without such approval.

SECTION 8.3 Extension of Time, Waiver, Etc. At any time prior to the Closing Date, any party may, subject to applicable Law, ( a) waive any inaccuracies in the representations and warranties of the other party hereto, (b) extend the time for the performance of any of the obligations or acts of the other party hereto or (c) waive compliance by any other party with any of the agreements contained herein or, except as otherwise provided herein, waive any of such party's conditions; provided that after the Company Stockholder Authorization is obtained, there may not be any extension or waiver of this Agreement or any portion thereof which, by Law or in accordance with the rules of any relevant stock exchange, requires further approval by such stockholders. Notwithstanding the foregoing, no failure or delay by the Company or Purchaser in exercising any right hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right hereunder. Any agreement on the part of a party hereto to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such party.

SECTION 8.4 Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned, in whole or in part, by any of the parties without the prior written consent of the other party; provided that such consent shall not be required (a) for assignments and transfers by operation of Law and (b) in the event the Company assigns any or all of its rights, interests and obligations hereunder to a Person with whom the Company merges or to whom the Company sells all or substantially all of its assets or to an Affiliate of Company. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the parties hereto and their respective successors and permitted assigns. Any purported assignment not permitted under this section shall be null and void.

SECTION 8.5 Counterparts. This Agreement may be executed in counterparts (each of which shall be deemed to be an original but both of which taken together shall constitute one and the same agreement) and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

SECTION 8.6 Entire Agreement: No Third Party Beneficiaries. This Agreement, together with the Schedules, the Disclosure Letter and the Confidentiality Agreement, (a) constitutes the entire agreement, and supersedes all other prior agreements and understandings, both written and oral, between the parties, or any of them, with respect to the subject matter hereof and thereof and (b) are not intended to and shall not confer upon any Person other than the parties hereto any rights or remedies hereunder.

SECTION 8.7 Governing Law; Submission to Jurisdiction; Appointment of Agent for Service of Process; Waiver of Jury Trial.

(a) This Agreement shall be governed by, and construed in accordance with, the Laws of the State of New Jersey, without regard to principles of conflict of Laws that would require the application of the Laws of another jurisdiction. The parties hereto hereby declare that it is their intention that this Agreement shall be regarded as made under the Laws of the State of New Jersey and that the Laws of said State shall be applied in interpreting its provisions in all cases where legal interpretation shall be required. Each of the parties hereto hereby irrevocably and unconditionally agrees (i) to be subject to the jurisdiction of the courts of the State of New Jersey and of the federal courts sitting in the State of New Jersey.



(b) The parties hereto hereby agree to bring all Actions and Proceedings arising out of or relating to this Agreement in the Courts of the State of New Jersey, and the parties irrevocably waive, to the fullest extent permitted by applicable Law, the defense of an inconvenient forum to the maintenance of any such Action or Proceeding. The parties hereto agree that a formal judgment in any such Action or Proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable Law.

(c) **EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT.**

**SECTION 8.8** Specific Enforcement. The parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall, to the fullest extent permitted by applicable Law, be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in the Chancery Court of the State of Delaware, without bond or other security being required, this being in addition to any other remedy to which they are entitled at Law or in equity.

**SECTION 8.9** Notices. All notices, requests and other communications to any party hereunder shall be in writing and shall be deemed given if delivered personally, facsimiled (which is confirmed) or sent by overnight courier (providing proof of delivery) to the parties at the following addresses:

If to Purchaser, to:

Attention

with a copy (which shall not constitute notice) to:

Attention:

If to the Company, to:

[COMPANY]

Attention:

with a copy (which shall not constitute notice) to:

or such other address or facsimile number as such party may hereafter specify for the purpose by notice to the other party hereto. All such notices, requests and other communications shall be deemed received on the date of receipt by the recipient thereof if received prior to 5 P.M. in the place of receipt and such day is a business day in the place of receipt. Otherwise, any such notice, request or communication shall be deemed not to have been received until the next succeeding business day in the place of receipt.

SECTION 8.10 Severability. If any term or other provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced by any rule of Law or public policy, all other terms, provisions and conditions of this Agreement shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible to the fullest extent permitted by applicable Law in an acceptable manner to the end that the Transaction is fulfilled to the extent possible.

SECTION 8.11 Definitions.

(a) As used in this Agreement, the following terms have the meanings ascribed thereto below:

" Action or Proceeding " shall mean any action, suit, proceeding, arbitration or Governmental Authority investigation.

" Affiliate " shall mean, as to any Person, any other Person that directly or indirectly controls, or is controlled by, or is under common control with, such Person. For this purpose, "control" (including, with its correlative meanings, "controlled by" and "under common control with") shall mean the possession, directly or indirectly, of the power to direct or cause the direction of management or policies of a Person, whether through the ownership of securities or partnership or other ownership interests, by Contract or otherwise.

" Cutanogen Liability " shall mean any Liability relating to, arising out of or resulting from any action, inaction, event, omission, condition, fact or circumstance occurring or existing prior to, on or after the Closing, in each case to the extent such Liability relates to, arises out of or results from any of the assets or property of Cutanogen.

" Material Adverse Effect " shall mean any change, event or occurrence which has a material adverse effect on the Cutanogen Business when taken as a whole, other than changes, events, occurrences or effects arising out of, resulting from or attributable to (i) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (ii) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles that, in each case, generally affect industries in which Cutanogen conducts business, provided that such changes do not affect Cutanogen in a disproportionate manner.

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

" Transaction " refers collectively to this Agreement and the transactions contemplated hereby to take place on the Closing Date, including the purchase and sale of the Cutanogen Shares.

" business day" shall mean a day except a Saturday, a Sunday or other day on which the SEC or banks in the City of New York are authorized or required by Law to be closed.

" Code" shall mean the Internal Revenue Code of 1986, as amended.

" Company Board" shall mean the board of directors of the Company or any duly constituted committee thereof which has been given the authority to act in the name, place and stead of the board of directors of the Company with respect to this Agreement, the Transaction and the transactions contemplated thereby.

" Company Common Stock " shall mean the voting common stock, \$0.10 par value, of the Company.

" Company Liability" shall mean any Liability of the Company.

" GAAP " shall mean generally accepted accounting principles in the United States.

" Governmental Authority" shall mean any government, court, regulatory or administrative agency, commission or authority or other governmental instrumentality, federal, state or local, domestic, foreign or multinational.

" HSR Act " shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

" Indebtedness " of any Person means all obligations of such Person (i) for borrowed money, (ii) evidenced by notes, bonds, debentures or similar instruments, (iii) under capital leases and (iv) in the nature of guarantees of the obligations described in clauses (i) through (iii) above of any other Person.

" Insurance Proceeds " shall mean those monies (i) received by an insured from an insurance carrier or (ii) paid by an insurance carrier on behalf of the insured, in either case net of any applicable premium adjustments, retrospectively rated premium adjustments, deductibles, retentions or costs paid by such insured.

" Knowledge " shall mean, in the case of either the Company or Purchaser, the actual knowledge, as of the date of this Agreement, of any of the executive officers of such party.

" Liabilities " shall mean any and all debts, liabilities and obligations, whether accrued or fixed, absolute or contingent, matured or unmatured, reserved or unreserved, or determined or determinable, including, without limitation, those arising under any Law, claim, demand, Action or Proceeding, whether asserted or unasserted, or judgment, writ or injunction of any Governmental Authority, and those arising under any Contract, arrangement, commitment or undertaking or any fines, damages or equitable relief which may be imposed and including, without limitation, all costs and expenses related thereto.

" Loss " shall mean any and all claims, actions, causes of action, Liabilities, losses, damages, and reasonable out-of-pocket expenses and costs.

" Person " shall mean an individual, a corporation, a limited liability company, a partnership, an association, a trust or any other entity, including a Governmental Authority.

" Subsidiary" when used with respect to any party, shall mean any corporation, limited liability company, partnership, association, trust or other entity of which securities or other ownership interests representing more than 50% of the equity and more than 50% of the ordinary voting power (or, in the case of a partnership, more than 50% of the general partnership interests) are, as of such date, owned by such party or one or more Subsidiaries of such party or by such party and one or more Subsidiaries of such party.

" Taxing Authority" means any Governmental Authority and any other quasigovernmental or non-governmental body administering, regulating or having general responsibility for the imposition of any Tax.

#### SECTION 8.12 Interpretation .

(a) The table of contents and headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the words " include", " includes" or " including " are used in this Agreement, they shall be deemed to be followed by the words " without limitation ". The words " hereof ", " herein " and " hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. All terms defined in this Agreement shall have the defined meanings when used in any document made or delivered pursuant hereto unless otherwise defined therein. The definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms and to the masculine as well as to the feminine and neuter genders of such term. Any agreement, instrument or statute defined or referred to herein or in any agreement or instrument that is referred to herein means such agreement, instrument or statute as from time to time amended, modified or supplemented, including (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein. References to a Person are also to its permitted successors and assigns.

(b) The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.

\* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment and those portions have been filed separately with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the date first above written.

**REGENICIN, INC.**

By:  
Name:  
Title:

**LONZA WALKERSVILLE, INC.**

By:  
Name:  
Title: