# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

-----

FORM 8-K

#### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

December 10, 2001
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc. (Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-26422 (Commission File Number) 94-3171943 (IRS Employer Identification Number)

350 Main Street, Suite 307 Doylestown, Pennsylvania 18901 (Address of principal executive offices)

(215) 340-4699 (Registrant's telephone number, including area code)

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

#### Item 5. Other Events

On December 11, 2001, Discovery Laboratories, Inc., a Delaware corporation ("Discovery"), issued a press release to announce that it had entered into a collaboration arrangement (the "Collaboration") with Quintiles Transnational Corp. ("Quintiles"), and its affiliate, PharmaBio Development Inc. ("PharmaBio"). In connection therewith, Discovery raised \$3.0 million in gross proceeds and issued (i) 791,905 shares of its common stock, par value \$.001 per share ("Common Stock") and (ii) warrants to purchase an aggregate of approximately 677,143 shares of Common Stock, subject to adjustment. After payment of fees and associated expenses, Discovery intends to use the net proceeds of approximately \$2.7 million, for working capital and general corporate purposes.

#### Transaction Overview

In connection with the Collaboration, Discovery entered into a series of agreements with Quintiles and PharmaBio. As further discussed below and subject to the terms and conditions set forth in the agreements, Quintiles agreed to provide certain commercialization services in the United States for Discovery's lead product candidate, Surfaxin(R), for the treatment of meconium aspiration syndrome ("MAS") and idiopathic respiratory distress syndrome ("IRDS"). In addition, PharmaBio agreed to fund up to \$70 million of the sales and marketing costs for Surfaxin for seven years of Surfaxin commercialization. In addition to the \$3.0 million equity investment in Discovery, PharmaBio also agreed to extend a line of credit of up to \$8.5 million to \$10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as Discovery achieves certain milestones. Principal amounts owed by Discovery under the credit facility may be repaid out of the proceeds of milestone payments to be paid by PharmaBio at certain intervals upon the achievement of certain corporate milestones that are discussed in greater detail below.

## Commercialization Arrangements

Pursuant to the commercialization agreement between Discovery and Quintiles (the "Commercialization Agreement"), Quintiles will provide pre- and post-launch marketing services for the promotion of Surfaxin for MAS or IRDS in the United States. Upon approval of Surfaxin by the United States Food and Drug Administration ("FDA") for sale in the United States for MAS or IRDS, Quintiles will hire and train a dedicated United States sales force that will be branded in the market as Discovery's. Quintiles also will provide certain management and administrative personnel to assist in the Collaboration. Among other things, Quintiles will provide a product manager to coordinate pre-launch marketing activities. Quintiles has been granted the opportunity to provide outsourced services to Discovery for the development of Surfaxin for the treatment of an acute respiratory distress syndrome ("ARDS") indication conditioned upon Quintiles' satisfaction of certain performance-related and competitive criteria regarding the provision of such services. In addition, Quintiles has been

granted a right of first negotiations solely as a preferred provider to provide competitive clinical trial development and commercialization services for other products that may be developed by Discovery and for which Discovery intends to outsource such services, whether related to Surfaxin or otherwise. Discovery will be responsible for order processing and fulfillment, invoicing and collection of accounts receivables from sales (which may upon agreement of Discovery and Quintiles be

performed by Quintiles or one of its affiliates). Discovery will also be responsible for supply and inventories of Surfaxin as well as regulatory and medical affairs. Under certain circumstances, Discovery has the option to hire the sales force created by Quintiles.

Pursuant to a related investment and commission agreement between PharmaBio and Discovery (the "Investment and Commission Agreement"), PharmaBio is obligated to pay 100% of specified sales and marketing expenses payable to Quintiles for services provided by it pursuant to the Commercialization Agreement. Following the commercial launch of Surfaxin for MAS or IRDS, such commitment is limited to a maximum of \$70 million over a seven-year period. In consideration therefor, Discovery has agreed to pay PharmaBio a commission on net sales in the United States of Surfaxin for MAS, IRDS and all "off-label" uses for 10 years following first launch of the product in the United States.

The Collaboration will be managed and governed by a joint commercialization committee (the "Joint Commercialization Committee"), consisting of an equal number of representatives appointed by Discovery and Quintiles. A Discovery representative will chair the Joint Commercialization Committee. Subject to certain exceptions, Discovery will have a tie-breaking vote on all matters to be considered by the Joint Commercialization Committee, and, accordingly, it has final decision-making control on all strategic issues regarding Surfaxin throughout the term of the Commercialization Agreement.

#### Credit Facility

In connection with the Collaboration, PharmaBio is providing to Discovery a secured revolving credit facility (the "Credit Facility"). Under the Credit Facility, PharmaBio has committed to advance on a revolving basis up to \$8.5 million, which may be increased to \$10 million, at the discretion of the Joint Commercialization Committee. Interest on the Credit Facility will be payable on a quarterly basis in arrears. Discovery is obligated to use a significant portion of the funds borrowed under the Credit Facility for pre-launch marketing services to be provided by Quintiles pursuant to the Commercialization Agreement.

The Credit Facility of \$8.5 million (subject to increase as stated above) will be available for borrowing by Discovery incrementally upon the occurrence of three milestones. One-third of the commitment will be available upon the later to occur of (i) the completion of a market opportunity assessment and report regarding Surfaxin and (ii) an extension for the deadline for the filing of a New Drug Application for Surfaxin with FDA ("NDA") under Discovery's license agreement for Surfaxin until at least October 28, 2003 ("Milestone One").

Provided that Milestone One has occurred, one-third of the commitment will be available for borrowing by Discovery upon the later to occur of (i) Discovery's successful completion of an aggregate of \$10 million capital raise for general corporate purposes or (ii) the public disclosure by Discovery of Phase III clinical trial data for IRDS, and the completion by Quintiles of a favorable written assessment and report regarding such data and Discovery ("Milestone Two").

Provided that Milestone One and Milestone Two have occurred, one-third of the commitment will be available for borrowing by Discovery upon the later to occur of (i) the completion by Quintiles of a written assessment and report indicating the "approvability" by FDA of Discovery's NDA for Surfaxin for either IRDS or MAS or (ii) the issuance by FDA of a

letter indicating that Discovery's NDA for Surfaxin is "approvable" with respect to Discovery's NDA for either IRDS or MAS.

Discovery is also entitled to two milestone payments under the Investment and Commission Agreement with PharmaBio, which will be used to offset and prepay principal amounts due under the Credit Facility.

Upon the occurrence of FDA approval for the commercialization of Surfaxin for MAS or IRDS, the first milestone payment will equal 70% of the outstanding amount of advances under the Credit Facility. Such milestone payment will be used to offset and prepay such advances, and the available commitment under the Credit Facility will be reduced by an equivalent amount.

Upon the earlier to occur of (i) the completion by Quintiles of a written assessment and report indicating the "approvability" by FDA of Discovery's NDA for Surfaxin for whichever of the MAS or IRDS indications was not approved previously, or (ii) the issuance by FDA of a letter indicating that Discovery's NDA for Surfaxin for such indication is "approvable," the second milestone payment will equal the outstanding amount of advances under the Credit Facility. Such milestone payment will be used to offset and prepay such advances, and the commitment under the Credit Facility will be terminated.

Notwithstanding the prepayment milestones, the Credit Facility will be payable in full on December 10, 2004.

Discovery's obligations to PharmaBio under the Credit Facility are secured by limited collateral relating to Surfaxin pursuant to a security agreement (the "Security Agreement"). The pledged collateral includes all revenues derived from sales in the United States of Surfaxin for MAS, IRDS and for ARDS, as well as all clinical data and regulatory filings relating thereto, but does not include any intellectual property rights. Upon the occurrence of FDA approval for the commercialization of Surfaxin for MAS or IRDS, all pledged collateral that relates to ARDS will be released by Quintiles.

#### **Equity Investment**

Pursuant to the common stock and warrant purchase agreement between PharmaBio and Discovery (the "Purchase Agreement"), PharmaBio purchased 791,905 shares of Common Stock at a price of \$3.79 per share. In addition, PharmaBio purchased two separate classes of warrants to purchase shares of Common Stock. Pursuant to the Class G warrant, PharmaBio may purchase 357,143 shares of Common Stock (subject to adjustment), at a price of \$3.485 per share. PharmaBio also purchased a Class H warrant to purchase 320,000 shares of Common Stock at a price of \$3.03 per share. The Class H warrant vests in three equal increments equal to one-third of the shares of Common Stock issuable thereunder, upon the occurrence of each of the three milestones pursuant to which the commitment under the Credit Facility becomes available. The Class G warrant and Class H warrant each expire on December 10, 2011. To the extent that the commitment under the Credit Facility is increased to an amount greater than \$8.5 million, the amount of shares of Common Stock issuable pursuant to the Class H warrant will increase proportionally. Accordingly, for each additional \$1 million that becomes available under the Credit Facility, the amount of shares of Common Stock issuable pursuant to the Class H warrant will be increased by approximately 38,500 shares.

The shares of Common Stock purchased by PharmaBio, or issuable pursuant to the Class G warrant and the Class H warrant, have not been registered under the Securities Act of 1933 (the "1933 Act") and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the 1933 Act. In addition, all such shares of Common Stock are subject to certain restrictions on transfer as set forth in the Purchase Agreement. PharmaBio will have up to two "demand" registration rights that require Discovery to register its shares of Common Stock for resale under the 1933 Act, including shares issuable pursuant to the Class G warrant and the Class H warrant. In addition, subject to certain limitations, PharmaBio has customary "piggyback" rights to include such shares of Common Stock in other registrations of securities filed by Discovery for resale under the 1933 Act.

PharmaBio has agreed to certain limitations on its trading of, and purchase of additional shares of, Common Stock, as well as certain prescriptions regarding the voting of its shares. PharmaBio also has the right pursuant to the Purchase Agreement to maintain its percentage equity ownership of Discovery by purchasing additional securities on the same terms as any transaction in which Discovery proposes to raise additional equity capital. Such right will be inapplicable to (i) underwritten public offerings, (ii) bona fide acquisitions, mergers, joint ventures, collaborative arrangements, strategic alliances or similar transactions, the terms of which are approved by Discovery's Board of Directors, or (iii) pursuant to any stock option, stock purchase or similar plan or arrangement for the benefit of Discovery's employees.

A copy of the press release announcing the execution of the agreements relating to the Collaboration, the Purchase Agreement, the Class G warrant, the Class H warrant, the Commercialization Agreement, the Investment and Commission Agreement, the Credit Facility, the related Promissory Note, and the Security Agreement are attached as exhibits hereto. The descriptions of the Collaboration contained in the attached press release and in this Item 5 do not purport to be complete and are qualified in their entirety by reference to the agreements and instruments attached as exhibits hereto.

To the extent that statements in this report are not strictly historical, including statements as to Discovery's business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of Discovery's product development, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements, risks that any collaborators may not perform their obligations under any such agreements, risks relating to the progress of Discovery's research and development and the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in Discovery's periodic filings with the Securities and Exchange Commission including its reports on Forms 10-KSB, 8-K and 10-QSB, and amendments thereto.

## Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

### (c) Exhibits:

- 4.1 Class G Warrant

- 4.2 Class H Warrant
  4.3 Promissory Note
  \*10.1 Commercialization Agreement
- \*10.2 Investment and Commission Agreement
- \*10.3 Common Stock and Warrant Purchase Agreement

- \*10.4 Loan Agreement
  10.5 Security Agreement
  99.1 Press Release dated December 11, 2001.
- \* Confidential treatment has been requested with respect to certain portions of these exhibits. Such portions have been separately filed with the of the Securities and Exchange Commission and redacted herein.

#### **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.

Discovery Laboratories, Inc.

By: /s/ Robert J. Capetola -----

Name: Robert J. Capetola, Ph.D. Title: President and Chief Executive Officer

Date: December 19, 2001

## Discovery Laboratories, Inc. Form 8-K Index to Exhibits

4.1	Class G Warrant
4.2	Class H Warrant
4.3	Promissory Note
*10.1	Commercialization Agreement
*10.2	Investment and Commission Agreement
*10.3	Common Stock and Warrant Purchase Agreement
*10.4	Loan Agreement
10.5	Security Agreement
99.1	Press Release dated December 11, 2001.

**DESCRIPTION** 

EXHIBIT NO.

<sup>\*</sup> Confidential treatment has been requested with respect to certain portions of these exhibits. Such portions have been separately filed with the of the Securities and Exchange Commission and redacted herein.

#### WARRANT AGREEMENT CLASS G

This WARRANT AGREEMENT is dated and entered into as of December 10, 2001, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("PharmaBio").

WHEREAS, the Company and PharmaBio have entered into a Common Stock and Warrant Purchase Agreement, dated as of the date hereof (the "Purchase Agreement"); and

WHEREAS, pursuant to the Purchase Agreement, the Company desires to grant to PharmaBio the rights set forth in this Warrant Agreement;

NOW, THEREFORE, in consideration of the mutual agreements, undertakings and covenants set forth in this Warrant Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

- 1. The Warrant. The Company hereby agrees to issue and sell to PharmaBio, its designee or assigns (the "Holder") up to Three Hundred Fifty-Seven Thousand, One Hundred Forty Three (357,143) shares (the "Warrant Shares") of the Company's common stock, par value \$.001 per share ("Common Stock"), at an exercise price of Three and 485/1000 Dollars (\$3.485) per share (the "Exercise Price") upon the terms and conditions herein set forth. The Exercise Price and the number of Warrant Shares purchasable upon exercise of this Warrant Agreement are subject to adjustment from time to time as provided in Section 4 of this Warrant Agreement.
- 2. Expiration Date. This Warrant Agreement, and the Holder's right to purchase any of the Warrant Shares, will expire at 5:00 p.m. Eastern Time on the tenth anniversary of the date of this Warrant Agreement (the "Expiration Date").
- 3. Exercise of this Warrant Agreement. (a) The Holder may exercise this Warrant Agreement at any time from and after the date hereof and prior to the  $\frac{1}{2}$ Expiration Date, in whole or in part, as adjusted from time to time as provided in Section 4 of this Warrant Agreement, by: (a) the surrender of this Warrant Agreement, with the Exercise Form in the form attached hereto as Annex A properly completed and executed, at the principal office of the Company on a Business Day, and (b) upon payment by the delivery on a Business Day of a certified check or official bank check or wire transfer of immediately available funds, payable to the order of the Company, in an amount equal to the aggregate purchase price for the Warrant Shares being purchased upon such exercise. Upon receipt thereof by the Company, the Holder will be deemed to be the holder of record of the Warrant Shares issuable upon such exercise as of the close of business on the date of such receipt by the Company, and the Company will promptly execute or cause to be executed and delivered to the Holder, a certificate or certificates representing the aggregate number of Warrant Shares specified in the Exercise Form. If this Warrant Agreement is exercised only in part, the Company will, at the time of delivery of said stock certificate or

certificates, deliver to the Holder a new Warrant Agreement of like tenor evidencing the right of the Holder to purchase the remaining Warrant Shares then covered by this Warrant Agreement. "Business Day" shall mean any day other than a Saturday, Sunday or legal holiday on which banks in North Carolina and New York are open for the conduct of their banking business.

(b) In lieu of exercising this Warrant Agreement, the Holder may elect to receive shares equal to the value of this Warrant Agreement (or the portion of the Warrant Shares thereunder being exercised) by sending written notice of such election to the Company, in which event the Company shall deliver to the Holder a stock certificate representing a number of shares of Common Stock computed using the following formula:

Where:

- X = the number of shares of Common Stock to be issued to the Holder
- Y = the number of shares of Common Stock purchasable under this Warrant Agreement as to which the Holder is then exercising this Warrant Agreement

- A = the fair market value of one share of Common Stock
- B =the Exercise Price (as adjusted to the date of such calculations)
- (c) For purposes of this Section, "fair market value" of one share of Common Stock shall mean the average of the closing sales price quoted on the Nasdaq SmallCap Market, Nasdaq National Market or the principal exchange on which the Common Stock is listed (or the closing bid price thereon if there is no such reported sales price for any trading day), or the closing bid and asked prices of the Common Stock quoted in the Over-The-Counter Market Summary, whichever is applicable, as published in the Eastern Edition of The Wall Street Journal, for the thirty (30) trading days prior to the date of determination of fair market value. If the Common Stock is not traded Over-The-Counter or on such market or exchange, the fair market value of the Common Stock will be the price per share which the Company could obtain from a willing buyer for shares sold by the Company from authorized but unissued shares, as agreed upon by the Company and the Holder in good faith or, absent such agreement, as shall be determined by arbitration instituted by either party under the rules of the American Arbitration Association. If this Warrant Agreement has not been exercised prior to the Expiration Date, the Holder shall be deemed to have elected on the Expiration Date to receive shares pursuant to Section 3(b).
- (d) In the event that after the first anniversary of the date of this Warrant Agreement, the average closing sales price of the Common Stock quoted on the Nasdaq SmallCap Market for any twenty (20) trading days in any thirty (30) consecutive trading-day period is at least Three Hundred percent (300%) of the Exercise Price, then the Company may give written notice to the Holder requesting that the Holder exercise this Warrant Agreement under Section 3(a) or that the Holder elect to receive shares pursuant to Section 3(b). Promptly following receipt of such notice, the Holder shall effect such exercise under Section 3(a) or make

such election under Section 3(b). If the Holder shall not have effected such exercise or made such election within ten (10) Business Days following the Company's notice, the Holder shall have been deemed to have made such election under Section 3(b) and this Warrant Agreement shall cease to represent the right to acquire any shares of Common Stock except pursuant to such deemed election.

- 4. Certain Adjustments. The Exercise Price at which Warrant Shares may be purchased and the number of Warrant Shares to be purchased upon exercise of this Warrant Agreement are subject to change or adjustment from time to time as follows:
- (a) Merger, Sale of Assets, etc. If at any time while this Warrant Agreement, or any portion hereof, is outstanding and unexpired there shall be (i) a reorganization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Company with or into another corporation or entity in which the Company is not the surviving entity, or a share exchange or reverse triangular merger in which the Company is the surviving entity but the shares of the Company's capital stock outstanding immediately prior to the merger are exchanged or converted by virtue of the merger into other property, whether in the form of securities, cash, or otherwise, or (iii) a sale, transfer or lease of all or substantially all of the Company's properties or assets to any other person or entity, then, as a part of such reorganization, merger, consolidation, sale or transfer, lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant Agreement, during the period specified herein and upon payment of the Exercise Price then in effect, the number of shares of stock or other securities or property resulting from such reorganization, merger, consolidation, sale or transfer that a holder of the shares deliverable upon exercise of this Warrant Agreement would have been entitled to receive in such reorganization, consolidation, merger, sale or transfer if this Warrant Agreement had been exercised immediately before such reorganization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 4. The foregoing provisions of this Section 4(a) shall similarly apply to successive reorganizations, consolidations, mergers, sales and transfers and to the stock or securities of any other corporation that are at the time receivable upon the exercise of this Warrant Agreement. If the per-share consideration payable to the Holder hereof for shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be reasonably determined in good faith by the Company's Board of Directors. In all events, appropriate adjustment (as reasonably determined in good faith by the Company's Board of Directors) shall be made in the application of the provisions of this Warrant Agreement with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Warrant Agreement shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable after that event upon exercise of this Warrant Agreement.
- (b) Reclassification, etc. If the Company, at any time while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, by reclassification of securities or otherwise, shall change any of the securities as to which purchase rights under this Warrant Agreement exist into the same or a different number of securities of any other class or classes, this Warrant Agreement shall thereafter represent the right to acquire such number and kind of securities as the Holder would have received if this Warrant Agreement had been

exercised in full immediately prior to such reclassification or other change or immediately prior to the record date with respect thereto and the Exercise Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Section 4. The foregoing provisions of this Section 4(b) shall similarly apply to successive reclassifications or other changes.

- (c) Split, Subdivision or Combination of Shares. If the Company, at any time while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, shall split, subdivide or combine the securities as to which purchase rights under this Warrant Agreement exist, into a different number of securities of the same class, the Exercise Price for such securities shall be proportionately decreased in the case of a split or subdivision or proportionately increased in the case of a combination. Upon each adjustment in the Exercise Price pursuant to this subsection, the number of shares of such securities purchasable hereunder shall be adjusted, to the nearest whole share, to the product obtained by multiplying the number of shares purchasable immediately prior to such adjustment in the Exercise Price by a fraction, the numerator of which shall be the Exercise Price immediately prior to such adjustment and the denominator of which shall be the Exercise Price immediately thereafter.
- (d) Adjustments for Dividends in Stock or Other Securities or Property. If while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, the holders of the securities as to which purchase rights under this Warrant Agreement exist at the time shall have received, or, on or after the record date fixed for the determination of eligible stockholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) by way of dividend, then and in each case, this Warrant Agreement shall represent the right to acquire, in addition to the number of shares of the security receivable upon exercise of this Warrant Agreement and, in addition, without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) that such holder would hold on the date of such exercise had it been the holder of record of the security receivable upon exercise of this Warrant Agreement on the date hereof and had thereafter, during the period from the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock or other securities or property (other than cash) available by or to it as aforesaid during such period, giving effect to all adjustments called for during such period by the provisions of this Section 5.
- (e) Certificate as to Adjustments. Upon the occurrence of each adjustment pursuant to this Section 4, the Company at its expense shall promptly compute such adjustment in accordance with the terms hereof and furnish to each Holder of this Warrant Agreement a certificate signed by its Chief Financial Officer setting forth such adjustment and showing in detail the event requiring the adjustment, the amount of such adjustment, the method by which such adjustment was calculated, the Exercise Price at the time in effect, and the number of shares and the amount, if any, of the property that at the time would be received upon the exercise of this Warrant Agreement, together with the facts upon which such adjustment is based. The Company shall, upon the reasonable written request of any such Holder, furnish or cause to be furnished to such Holder a like certificate setting forth: (i) all such previous adjustments; (ii) the Exercise Price at the time in effect; and (iii) the number of shares and the amount, if any, of other property that at the time would be received upon the exercise of this Warrant Agreement.

- (f) No Impairment. The Company will not, by amendment of its certificate of incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the intent of this Section 4 or the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Section 4 and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the holder of this Warrant Agreement against impairment. In case any event shall occur as to which the other provisions of this Section 4 are not strictly applicable but as to which the failure to make any adjustment would not fairly protect the purchase rights represented by this Warrant Agreement in accordance with the essential intent and principles hereof, then, in each such case, the Board of Directors of the Company shall in good faith determine the adjustment, if any, on a basis consistent with the purchase rights represented by this Warrant Agreement. Upon such determination, the Company will promptly deliver a copy thereof to the Holder and shall make the adjustments described therein.
- (g) No Adjustment. No adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least \$0.05 per share of Common Stock; provided, however, that any adjustments which by reason of this subsection 4(g) are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 4 shall be made to the nearest cent or to the nearest 1/100th of a share, as the case may be.
- 5. Fractional Shares. Upon the exercise of this Warrant Agreement, fractional shares may be issued by the Company, but the Company may, in lieu of issuing such fractional shares, pay a sum in cash equal to the excess of the fair market value of such fractional share (determined in such reasonable manner as may be prescribed by the Board of Directors of the Company in its discretion) over the proportional part of the per share purchase price represented by such fractional share.
  - 6. Intentionally Omitted
  - 7. Notices of Certain Events.

In case:

- (a) the Company shall take a record of the holders of its Common Stock (or other stock or securities at the time receivable upon the exercise of this Warrant Agreement) for the purpose of entitling them to receive any dividend or other distribution, or stock subdivision or combination, or any right to subscribe for or purchase any shares of stock of any class or any other securities, or to receive any other right, or
- (b) of any capital reorganization of the Company, any reclassification of the capital stock of the Company, any consolidation or merger of the Company with or into another corporation in which the Company is not the surviving corporation, or any conveyance of all or substantially all of the assets of the Company to another corporation, or

(c) of any voluntary dissolution, liquidation or winding-up of the Company,

then, and in each such case, the Company will cause notice thereof to be delivered to the Holder a notice specifying, as the case may be, (A) the date on which a record is to be taken for the purpose of such dividend, distribution or right, and stating the amount and character of such dividend, distribution or right, or (B) the date on which such reorganization, reclassification, consolidation, merger, conveyance, dissolution, liquidation or winding-up is to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such stock or securities at the time receivable upon the exercise of this Warrant Agreement) shall be entitled to exchange their shares of Common Stock (or such other stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, conveyance, dissolution, liquidation or winding-up. Such notice shall be delivered at least fifteen (15) days prior to the date therein specified.

- 8. Reservation of Shares. The Company will at all times until the date of exercise of this Warrant Agreement in full (the "Exercise Date") reserve and keep available out of its authorized but unissued stock, for the purpose of effecting the exercise of this Warrant Agreement, such number of its duly authorized shares of capital stock for which this Warrant Agreement is exercisable, and the appropriate number of shares of any stock into which such stock is convertible, if applicable, as will from time to time be sufficient to effect the exercise of this Warrant Agreement. The Company will from time to time take all steps necessary to amend its certificate of incorporation to provide at all times prior to the Exercise Date sufficient reserves of shares of common stock issuable upon exercise of this Warrant Agreement. If the number of authorized but unissued shares of common stock shall not be sufficient to effect the exercise the entire amount of this Warrant Agreement on the Exercise Date, in addition to such other remedies as shall be available to the Holder, the Company shall take all such corporate action as is necessary to increase its authorized but unissued shares of Common Stock and such number of shares as shall be sufficient for such purposes.
- 9. No Rights as Stockholder; Limitation of Liability. This Warrant Agreement, as distinct from the shares for which this Warrant Agreement is exercisable, will not entitle the Holder to any of the rights of a stockholder of the Company, including without limitation any right to vote on or consent to or receive notice as a stockholder of the Company, as such, in respect of any matters whatsoever. No provision of this Warrant Agreement, prior to the exercise of this Warrant Agreement, and no mere enumeration herein of the rights or privileges of the Holder, will give rise to any liability of the Holder for the purchase price or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

#### 10. Transfer Restrictions.

(a) Securities Laws. Neither this Warrant Agreement nor the securities issuable upon exercise hereof have been registered under the Securities Act of 1933, as amended (the "Securities Act"), or the securities laws of any state. Neither this Warrant Agreement nor the securities issuable upon exercise hereof nor any interest or participation herein or therein may be sold, assigned, pledged, hypothecated, encumbered or in any other manner transferred or

disposed of except in compliance with the Securities Act, the securities laws of each relevant state, and the terms and conditions hereof.

(b) Stock Certificate Legend. Each certificate for shares issued upon exercise of this Warrant Agreement will bear the following legend:

"The shares represented by this certificate have been acquired for investment and have not been registered under the Securities Act of 1933, as amended, or the securities laws of any state. Neither the shares nor any interest or participation in the shares may be sold, assigned, pledged, hypothecated, encumbered or in any other manner transferred or disposed of in the absence of such registration or exemption therefrom under such Act or such laws."

- (c) Purchase Agreement Restrictions. The provisions of Article VIII of the Purchase Agreement shall be applicable to the Warrant Shares to the same extent applicable to the Shares referred to therein.
- (d) Certain Representations and Warranties. The Holder hereby makes the representations and warranties set forth in Article V of the Purchase Agreement. Upon each exercise of this Warrant Agreement, the Holder shall be deemed to make the representations and warranties set forth in Article V of the Purchase Agreement to the extent necessary to afford the Company an exemption from registration under applicable federal and state securities laws.
- 11. Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the Securities and Exchange Commission ("SEC") that may permit the sale of securities to the public without registration, the Company agrees to use its reasonable best efforts to make and keep public information regarding the Company available as contemplated by Rule 144 under the Securities Act and file with the SEC in a timely manner all reports and other documents required by the Company under the Securities Act and the Securities Exchange Act of 1934, and furnish to the holder upon written request as to the Company's compliance with the reporting requirements of Rule 144 and of the Securities Act and the Securities Exchange Act of 1934.
- 12. Registration Rights. The Holder shall have the right to participate in the registration rights granted to holders of Registrable Securities under the Purchase Agreement.

#### 13. Miscellaneous.

- (a) Amendments and Waivers. This Warrant Agreement and any provision hereof may be amended, changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the same is sought.
- (b) Loss, Theft, Destruction or Mutilation. Upon receipt by the Company of evidence reasonably satisfactory to it that this Warrant Agreement has been lost, stolen, destroyed or mutilated, and in the case of any lost, stolen or destroyed Warrant Agreement, an indemnity reasonably satisfactory to the Company, or in the case of a mutilated Warrant

Agreement, upon surrender and cancellation hereof, the Company will execute and deliver in the name of the registered holder of this Warrant Agreement, in exchange and substitution for the Warrant Agreement so lost, stolen, destroyed or mutilated, a new Warrant Agreement of like tenor and amount.

- (c) Law Governing. This Warrant Agreement will be governed by, and construed and enforced in accordance with, the internal laws of the State of Delaware. Holder and the Company hereby irrevocably consent to the exclusive personal jurisdiction of any state or federal courts located in Delaware, in any action, claim or other proceeding arising out of any dispute in connection with this Warrant Agreement, any rights or obligations hereunder or the performance of such rights and obligations. The Holder and the Company waive their respective rights to a jury trial with respect to any action, claim, or other proceeding arising out of any dispute in connection with this Warrant Agreement, any rights or obligations hereunder, or the performance of such rights and obligations. The Holder and the Company agree that disputes relating to this Warrant Agreement shall be subject to the provisions of the Purchase Agreement entitled "Internal Review" and "Arbitration" set forth in Section 9.13 and 9.14 thereof, respectively.
- (d) Entire Agreement. This Warrant Agreement constitutes the full and entire understanding and agreement among the parties with regard to the subject matter of this Warrant Agreement, and supersedes all prior agreements, understandings, inducements or conditions, express or implied, oral or written, with respect to the subject matter of this Warrant Agreement.
- (e) Notices. Unless otherwise provided herein, all notices, requests, demands and other communications required or permitted under this Warrant Agreement shall be in writing and will be deemed to have been duly made and received: (i) upon personal delivery; (ii) three (3) Business Days after deposit with the United States Post Office, by registered or certified mail or by first class mail, postage prepaid, addressed as set forth below; or (iii) one (1) Business Day after deposit with a nationally recognized, overnight courier (for next business day delivery), shipping prepaid, addressed as set forth below:
  - (i) If to the Company, then to:

Discovery Laboratories, Inc. 350 South Main Street, Suite 307 Doylestown, PA 18901-4874 Attn: President

with a copy to:

Roberts, Sheridan & Kotel The New York Practice of Dickstein Shapiro's Corporate & Finance Group 1177 Avenue of the Americas New York, NY 10036-2714 Attn: Ira L. Kotel

## (ii) If to PharmaBio, then to:

PharmaBio Development Inc. 4709 Creekstone Drive Riverburch Building Suite 200 Durham, NC 27703 Attn: President

with a copy to:

PharmaBio Development Inc. 4709 Creekstone Drive Riverbirch Building Suite 200 Durham, NC 27703 Attn: General Counsel

Either party may change the address to which communications are to be sent by giving five (5) Business Days' advance notice of such change of address to the other party in conformity with the provisions of this Section.

(f) Execution; Counterparts. This Warrant Agreement may be executed in any number of counterparts, each of which will be deemed to be an original, and all of which will together constitute one and the same instrument. This Warrant Agreement may be executed and delivered by telecopy or facsimile and any execution in such manner shall be deemed an original.

[Signature on Following Page]

# [Signature Page to Warrant Agreement]

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

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

-----

Name: David L. Lopez

Title: Vice President and General Counsel

PHARMABIO DEVELOPMENT INC.

By: /s/ Thomas C. Perkins

Name: Thomas C. Perkins

Title: Vice President and General Counsel

# ANNEX A

# EXERCISE FORMS

# TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THE ATTACHED WARRANT AGREEMENT OF

DISCOVERY LABORATORIES, INC.

## SUBSCRIPTION

The undersigned,, pursiforegoing Warrant Agreement, hereby elects to exer agreeing to subscribe for and purchase	cise such Warrant Agreement by shares (the "Warrant e, of Discovery Laboratories, \$ by certified or Ly available funds payable to
The undersigned acknowledges that the sale, hypothecation of the Warrant Shares to be issued a Agreement is subject to the terms and conditions of undersigned further acknowledges that the sale, to hypothecation of the Warrant Shares to be issued a Agreement is subject to the terms and conditions of Warrant Agreement.	upon exercise of this Warrant of the Warrant Agreement. The ransfer, assignment or upon exercise of the Warrant
Dated: Signature:	
Address:_	

# ASSIGNMENT

FOR VALUE RECEIVED  transfers unto all rights evidenced thereby, and does i, attorney, to tra books of Discovery Laboratories, Inc. (t	_ the foregoing Warrant Agreement and rrevocably constitute and appoint nsfer said Warrant Agreement on the
	Signature:

# PARTIAL ASSIGNMENT

unto the rig Common Stock, par value \$.001 per share	ng Warrant Agreement, and a proportionate rights evidenced thereby, and does, attorney to transfer
Dated:	Signature:

#### WARRANT AGREEMENT CLASS H

This WARRANT AGREEMENT is dated and entered into as of December 10, 2001, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("PharmaBio").

WHEREAS, the Company and PharmaBio have entered into a Common Stock and Warrant Purchase Agreement dated as of the date hereof (the "Purchase Agreement") and a Loan Agreement dated as of the date hereof (the "Loan Agreement"); and

WHEREAS, pursuant to the Purchase Agreement, the Company desires to grant to PharmaBio the rights set forth in this Warrant Agreement;

NOW, THEREFORE, in consideration of the mutual agreements, undertakings and covenants set forth in this Warrant Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

- 1. The Warrant. (a) The Company hereby agrees to issue and sell to PharmaBio, its designee or assigns (the "Holder") up to Three Hundred Twenty Thousand (320,000) shares (the "Warrant Shares") of the Company's common stock, par value \$.001 per share ("Common Stock"), at an exercise price of Three and 03/100 Dollars (\$3.03) per share (the "Exercise Price") subject to the vesting schedule in Section 1(b), and upon the terms and conditions herein set forth. The Exercise Price and the number of Warrant Shares purchasable upon exercise of this Warrant Agreement are subject to adjustment from time to time as provided in Section 4 of this Warrant Agreement.
- (b) The Holder's right to exercise this Warrant Agreement will vest in three (3) equal installments of one-third (1/3) of the Warrant Shares each (each an "Increment") as follows: the first Increment shall vest upon the occurrence of Milestone One as defined in the Loan Agreement; the second Increment shall vest upon the occurrence of Milestone Two as defined in the Loan Agreement; and the third Increment shall vest upon the occurrence of Milestone Three as defined in the Loan Agreement.
- (c) In the event that the maximum Commitment (as defined in the Loan Agreement) is increased to an amount in excess of \$8,500,000, then the number of Warrant Shares shall be increased (the "Warrant Increase") by a number of shares of Common Stock equal to the number of Warrant Shares set forth in Section 1(a) multiplied by a fraction, the numerator of which shall be the amount by which the Commitment is increased over \$8,500,000, and the denominator of which is \$8,500,000; provided, however, that if the Commitment is increased to an amount over \$15,000,000, then the amount in excess of \$15,000,000 shall not result in any Warrant Increase. The parties agree to negotiate in good faith to reach mutually acceptable terms and conditions for any Commitment in excess of \$15,000,000. Upon any

increase in Warrant Shares pursuant to this Section 1(c), each Increment shall be increased by one-third of the amount of such increase in Warrant Shares.

- 2. Expiration Date. This Warrant Agreement, and the Holder's right to purchase any of the Warrant Shares, will expire at 5:00 p.m. Eastern Time on the tenth anniversary of the date of this Warrant Agreement (the "Expiration Date").
- 3. Exercise of this Warrant Agreement. (a) The Holder may exercise this Warrant Agreement at any time from and after the date hereof and prior to the Expiration Date, in whole or in part, as adjusted from time to time as provided in Section 4 of this Warrant Agreement, by: (a) the surrender of this Warrant Agreement, with the Exercise Form in the form attached hereto as Annex A properly completed and executed, at the principal office of the Company on a Business Day, and (b) upon payment by the delivery on a Business Day of a certified check or official bank check or wire transfer of immediately available funds, payable to the order of the Company, in an amount equal to the aggregate purchase price for the Warrant Shares being purchased upon such exercise. Upon receipt thereof by the Company, the Holder will be deemed to be the holder of record of the Warrant Shares issuable upon such exercise as of the close of business on the date of such receipt by the Company, and the Company will promptly execute or cause to be executed and delivered to the Holder, a certificate or certificates representing the aggregate number of Warrant Shares specified in the Exercise Form. If this Warrant Agreement is exercised only in part, the Company will, at the time of delivery of said stock certificate or certificates, deliver to the Holder a new Warrant Agreement of like tenor

evidencing the right of the Holder to purchase the remaining Warrant Shares then covered by this Warrant Agreement. "Business Day" shall mean any day other than a Saturday, Sunday or legal holiday on which banks in North Carolina and New York are open for the conduct of their banking business.

(b) In lieu of exercising this Warrant Agreement, the Holder may elect to receive shares equal to the value of this Warrant Agreement (or the portion of the Warrant Shares thereunder being exercised) by sending written notice of such election to the Company, in which event the Company shall deliver to the Holder a stock certificate representing a number of shares of Common Stock computed using the following formula:

#### Where:

- X = the number of shares of Common Stock to be issued to the Holder
- Y = the number of shares of Common Stock purchasable under this Warrant Agreement as to which the Holder is then exercising this Warrant Agreement
- A = the fair market value of one share of Common Stock
- B = the Exercise Price (as adjusted to the date of such calculations)

- (c) For purposes of this Section, "fair market value" of one share of Common Stock shall mean the average of the closing sales price quoted on the Nasdaq SmallCap Market, Nasdaq National Market or the principal exchange on which the Common Stock is listed, (or the closing bid price thereon if there is no such reported sales price for any trading day), or the closing bid and asked prices of the Common Stock quoted in the Over-The-Counter Market Summary, whichever is applicable, as published in the Eastern Edition of The Wall Street Journal, for the thirty (30) trading days prior to the date of determination of fair market value. If the Common Stock is not traded Over-The-Counter or on such market or exchange, the fair market value of the Common Stock will be the price per share which the Company could obtain from a willing buyer for shares sold by the Company from authorized but unissued shares, as agreed upon by the Company and the Holder in good faith or, absent such agreement, as shall be determined by arbitration instituted by either party under the rules of the American Arbitration Association. If this Warrant Agreement has not been exercised prior to the Expiration Date, the Holder shall be deemed to have elected on the Expiration Date to receive shares pursuant to Section 3(b).
- (d) In the event that after the first anniversary of the date of this Warrant Agreement, the average closing sales price of the Common Stock quoted on the Nasdaq SmallCap Market for any twenty (20) trading days in any thirty (30) consecutive trading-day period is at least Four Hundred percent (400%) of the Exercise Price, then the Company may give written notice to the Holder requesting that the Holder exercise this Warrant Agreement under Section 3(a) or that the Holder elect to receive shares pursuant to Section 3(b). Promptly following receipt of such notice, the Holder shall effect such exercise under Section 3(a) or make such election under Section 3(b). If the Holder shall not have effected such exercise or made such election within ten (10) Business Days following the Company's notice, the Holder shall have been deemed to have made such election under Section 3(b) and this Warrant Agreement shall cease to represent the right to acquire any shares of Common Stock except pursuant to such deemed election.
- 4. Certain Adjustments. The Exercise Price at which Warrant Shares may be purchased and the number of Warrant Shares to be purchased upon exercise of this Warrant Agreement are subject to change or adjustment from time to time as follows:
- (a) Merger, Sale of Assets, etc. If at any time while this Warrant Agreement, or any portion hereof, is outstanding and unexpired there shall be (i) a reorganization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Company with or into another corporation or entity in which the Company is not the surviving entity, or a share exchange or reverse triangular merger in which the Company is the surviving entity but the shares of the Company's capital stock outstanding immediately prior to the merger are exchanged or converted by virtue of the merger into other property, whether in the form of securities, cash, or otherwise, or (iii) a sale, transfer or lease of all or substantially all of the Company's properties or assets to any other person or entity, then, as a part of such reorganization, merger, consolidation. sale or transfer, lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant Agreement, during the period specified herein and upon payment of the Exercise Price then in effect, the number of shares of stock or other securities or property resulting from such reorganization, merger, consolidation, sale or transfer that a holder of the shares deliverable upon

exercise of this Warrant Agreement would have been entitled to receive in such reorganization, consolidation, merger, sale or transfer if this Warrant Agreement had been exercised immediately before such reorganization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 4. The foregoing provisions of this Section 4(a) shall similarly apply to successive reorganizations, consolidations, mergers, sales and transfers and to the stock or securities of any other corporation that are at the time receivable upon the exercise of this Warrant Agreement. If the per-share consideration payable to the Holder hereof for shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be reasonably determined in good faith by the Company's Board of Directors. In all events, appropriate adjustment (as reasonably determined in good faith by the Company's Board of Directors) shall be made in the application of the provisions of this Warrant Agreement with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Warrant Agreement shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable after that event upon exercise of this Warrant Agreement.

- (b) Reclassification, etc. If the Company, at any time while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, by reclassification of securities or otherwise, shall change any of the securities as to which purchase rights under this Warrant Agreement exist into the same or a different number of securities of any other class or classes, this Warrant Agreement shall thereafter represent the right to acquire such number and kind of securities as the Holder would have received if this Warrant Agreement had been exercised in full immediately prior to such reclassification or other change or immediately prior to the record date with respect thereto and the Exercise Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Section 4. The foregoing provisions of this Section 4(b) shall similarly apply to successive reclassifications or other changes.
- (c) Split, Subdivision or Combination of Shares. If the Company, at any time while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, shall split, subdivide or combine the securities as to which purchase rights under this Warrant Agreement exist, into a different number of securities of the same class, the Exercise Price for such securities shall be proportionately decreased in the case of a split or subdivision or proportionately increased in the case of a combination. Upon each adjustment in the Exercise Price pursuant to this subsection, the number of shares of such securities purchasable hereunder shall be adjusted, to the nearest whole share, to the product obtained by multiplying the number of shares purchasable immediately prior to such adjustment in the Exercise Price by a fraction, the numerator of which shall be the Exercise Price immediately prior to such adjustment and the denominator of which shall be the Exercise Price immediately thereafter.
- (d) Adjustments for Dividends in Stock or Other Securities or Property. If while this Warrant Agreement, or any portion hereof, remains outstanding and unexpired, the holders of the securities as to which purchase rights under this Warrant Agreement exist at the time shall have received, or, on or after the record date fixed for the determination of eligible stockholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) by way of dividend, then and in each case,

this Warrant Agreement shall represent the right to acquire, in addition to the number of shares of the security receivable upon exercise of this Warrant Agreement and, in addition, without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) that such holder would hold on the date of such exercise had it been the holder of record of the security receivable upon exercise of this Warrant Agreement on the date hereof and had thereafter, during the period from the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock or other securities or property (other than cash) available by or to it as aforesaid during such period, giving effect to all adjustments called for during such period by the provisions of this Section 5.

- (e) Certificate as to Adjustments. Upon the occurrence of each adjustment pursuant to this Section 4, the Company at its expense shall promptly compute such adjustment in accordance with the terms hereof and furnish to each Holder of this Warrant Agreement a certificate signed by its Chief Financial Officer setting forth such adjustment and showing in detail the event requiring the adjustment, the amount of such adjustment, the method by which such adjustment was calculated, the Exercise Price at the time in effect, and the number of shares and the amount, if any, of the property that at the time would be received upon the exercise of this Warrant Agreement, together with the facts upon which such adjustment is based. The Company shall, upon the reasonable written request of any such Holder, furnish or cause to be furnished to such Holder a like certificate setting forth: (i) all such previous adjustments; (ii) the Exercise Price at the time in effect; and (iii) the number of shares and the amount, if any, of other property that at the time would be received upon the exercise of this Warrant Agreement.
- (f) No Impairment. The Company will not, by amendment of its certificate of incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the intent of this Section 4 or the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Section 4 and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the holder of this Warrant Agreement against impairment. In case any event shall occur as to which the other provisions of this Section 4 are not strictly applicable but as to which the failure to make any adjustment would not fairly protect the purchase rights represented by this Warrant Agreement in accordance with the essential intent and principles hereof, then, in each such case, the Board of Directors of the Company shall in good faith determine the adjustment, if any, on a basis consistent with the purchase rights represented by this Warrant Agreement. Upon such determination, the Company will promptly deliver a copy thereof to the Holder and shall make the adjustments described therein.
- (g) No Adjustment. No adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least \$0.05 per share of Common Stock; provided, however, that any adjustments which by reason of this subsection 4(g) are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 4 shall be made to the nearest cent or to the nearest 1/100th of a share, as the case may be.

- 5. Fractional Shares. Upon the exercise of this Warrant Agreement, fractional shares may be issued by the Company, but the Company may, in lieu of issuing such fractional shares, pay a sum in cash equal to the excess of the fair market value of such fractional share (determined in such reasonable manner as may be prescribed by the Board of Directors of the Company in its discretion) over the proportional part of the per share purchase price represented by such fractional share.
  - 6. Intentionally Omitted
  - 7. Notices of Certain Events.

In case:

- (a) the Company shall take a record of the holders of its Common Stock (or other stock or securities at the time receivable upon the exercise of this Warrant Agreement) for the purpose of entitling them to receive any dividend or other distribution, or stock subdivision or combination, or any right to subscribe for or purchase any shares of stock of any class or any other securities, or to receive any other right, or
- (b) of any capital reorganization of the Company, any reclassification of the capital stock of the Company, any consolidation or merger of the Company with or into another corporation in which the Company is not the surviving corporation, or any conveyance of all or substantially all of the assets of the Company to another corporation, or
- $% \left( c\right) =\left( c\right) =\left( c\right)$  (c) of any voluntary dissolution, liquidation or winding-up of the Company,

then, and in each such case, the Company will cause notice thereof to be delivered to the Holder a notice specifying, as the case may be, (A) the date on which a record is to be taken for the purpose of such dividend, distribution or right, and stating the amount and character of such dividend, distribution or right, or (B) the date on which such reorganization, reclassification, consolidation, merger, conveyance, dissolution, liquidation or winding-up is to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such stock or securities at the time receivable upon the exercise of this Warrant Agreement) shall be entitled to exchange their shares of Common Stock (or such other stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, conveyance, dissolution, liquidation or winding-up. Such notice shall be delivered at least fifteen (15) days prior to the date therein specified.

8. Reservation of Shares. The Company will at all times until the date of exercise of this Warrant Agreement in full (the "Exercise Date") reserve and keep available out of its authorized but unissued stock, for the purpose of effecting the exercise of this Warrant Agreement, such number of its duly authorized shares of capital stock for which this Warrant Agreement is exercisable, and the appropriate number of shares of any stock into which such stock is convertible, if applicable, as will from time to time be sufficient to effect the exercise of this Warrant Agreement. The Company will from time to time take all steps necessary to amend its certificate of incorporation to provide at all times prior to the Exercise Date sufficient reserves of shares of common stock issuable upon exercise of this Warrant Agreement. If the number of authorized but unissued shares of common stock shall not be sufficient to effect the exercise the

entire amount of this Warrant Agreement on the Exercise Date, in addition to such other remedies as shall be available to the Holder, the Company shall take all such corporate action as is necessary to increase its authorized but unissued shares of Common Stock and such number of shares as shall be sufficient for such purposes.

9. No Rights as Stockholder; Limitation of Liability. This Warrant Agreement, as distinct from the shares for which this Warrant Agreement is exercisable, will not entitle the Holder to any of the rights of a stockholder of the Company, including without limitation any right to vote on or consent to or receive notice as a stockholder of the Company, as such, in respect of any matters whatsoever. No provision of this Warrant Agreement, prior to the exercise of this Warrant Agreement, and no mere enumeration herein of the rights or privileges of the Holder, will give rise to any liability of the Holder for the purchase price or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

### 10. Transfer Restrictions.

- (a) Securities Laws. Neither this Warrant Agreement nor the securities issuable upon exercise hereof have been registered under the Securities Act of 1933, as amended (the "Securities Act"), or the securities laws of any state. Neither this Warrant Agreement nor the securities issuable upon exercise hereof nor any interest or participation herein or therein may be sold, assigned, pledged, hypothecated, encumbered or in any other manner transferred or disposed of except in compliance with the Securities Act, the securities laws of each relevant state, and the terms and conditions hereof.
- (b) Stock Certificate Legend. Each certificate for shares issued upon exercise of this Warrant Agreement will bear the following legend:

"The shares represented by this certificate have been acquired for investment and have not been registered under the Securities Act of 1933, as amended, or the securities laws of any state. Neither the shares nor any interest or participation in the shares may be sold, assigned, pledged, hypothecated, encumbered or in any other manner transferred or disposed of in the absence of such registration or exemption therefrom under such Act or such laws."

- (c) Purchase Agreement Restrictions. The provisions of Article VIII of the Purchase Agreement shall be applicable to the Warrant Shares to the same extent applicable to the shares referred to therein.
- (d) Certain Representations and Warranties. The Holder hereby makes the representations and warranties set forth in Article V of the Purchase Agreement. Upon each exercise of this Warrant Agreement, the Holder shall be deemed to make the representations and warranties set forth in Article V of the Purchase Agreement to the extent necessary to afford the Company an exemption from registration under applicable federal and state securities laws.

- 11. Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the Securities and Exchange Commission ("SEC") that may permit the sale of securities to the public without registration, the Company agrees to use its reasonable best efforts to make and keep public information regarding the Company available as contemplated by Rule 144 under the Securities Act and file with the SEC in a timely manner all reports and other documents required by the Company under the Securities Act and the Securities Exchange Act of 1934, and furnish to the holder upon written request as to the Company's compliance with the reporting requirements of Rule 144 and of the Securities Act and the Securities Exchange Act of 1934.
- 12. Registration Rights. The Holder shall have the right to participate in the registration rights granted to holders of Registrable Securities under the Purchase Agreement.

#### 13. Miscellaneous.

- (a) Amendments and Waivers. This Warrant Agreement and any provision hereof may be amended, changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the same is sought.
- (b) Loss, Theft, Destruction or Mutilation. Upon receipt by the Company of evidence reasonably satisfactory to it that this Warrant Agreement has been lost, stolen, destroyed or mutilated, and in the case of any lost, stolen or destroyed Warrant Agreement, an indemnity reasonably satisfactory to the Company, or in the case of a mutilated Warrant Agreement, upon surrender and cancellation hereof, the Company will execute and deliver in the name of the registered holder of this Warrant Agreement, in exchange and substitution for the Warrant Agreement so lost, stolen, destroyed or mutilated, a new Warrant Agreement of like tenor and amount.
- (c) Law Governing. This Warrant Agreement will be governed by, and construed and enforced in accordance with, the internal laws of the State of Delaware. Holder and the Company hereby irrevocably consent to the exclusive personal jurisdiction of any state or federal courts located in Delaware, in any action, claim or other proceeding arising out of any dispute in connection with this Warrant Agreement, any rights or obligations hereunder or the performance of such rights and obligations. The Holder and the Company waive their respective rights to a jury trial with respect to any action, claim, or other proceeding arising out of any dispute in connection with this Warrant Agreement, any rights or obligations hereunder, or the performance of such rights and obligations. The Holder and the Company agree that disputes relating to this Warrant Agreement shall be subject to the provisions of the Purchase Agreement entitled "Internal Review" and "Arbitration" set forth in Sections 9.13 and 9.14 thereof, respectively.
- (d) Entire Agreement. This Warrant Agreement constitutes the full and entire understanding and agreement among the parties with regard to the subject matter of this Warrant Agreement, and supersedes all prior agreements, understandings, inducements or conditions, express or implied, oral or written, with respect to the subject matter of this Warrant Agreement.

(e) Notices. Unless otherwise provided herein, all notices, requests, demands and other communications required or permitted under this Warrant Agreement shall be in writing and will be deemed to have been duly made and received: (i) upon personal delivery; (ii) three (3) Business Days after deposit with the United States Post Office, by registered or certified mail or by first class mail, postage prepaid, addressed as set forth below; or (iii) one (1) Business Day after deposit with a nationally recognized, overnight courier (for next business day delivery), shipping prepaid, addressed as set forth below:

# (i) If to the Company, then to:

Discovery Laboratories, Inc. 350 South Main Street Suite 307 Doylestown, PA 18901-4874 Attn: President

with a copy to:

Roberts, Sheridan & Kotel The New York Practice of Dickstein Shapiro's Corporate & Finance Group 1177 Avenue of the Americas New York, NY 10036-2714 Attn: Ira L. Kotel

## (ii) If to PharmaBio, then to:

PharmaBio Development Inc. 4709 Creekstone Drive Riverburch Building Suite 200 Durham, NC 27703 Attn: President

with a copy to:

PharmaBio Development Inc. 4709 Creekstone Drive Riverbirch Building Suite 200 Durham, NC 27703 Attn: General Counsel Either party may change the address to which communications are to be sent by giving five (5) Business Days' advance notice of such change of address to the other party in conformity with the provisions of this Section.

(f) Execution; Counterparts. This Warrant Agreement may be executed in any number of counterparts, each of which will be deemed to be an original, and all of which will together constitute one and the same instrument. This Warrant Agreement may be executed and delivered by telecopy or facsimile and any execution in such manner shall be deemed an original.

[Signature on Following Page]

# [Signature Page to Warrant Agreement]

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

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

\_\_\_\_\_

Name: David L. Lopez

Title: Vice President and General Counsel

PHARMABIO DEVELOPMENT INC.

By: /s/ Thomas C. Perkins

Name: Thomas C. Perkins

Title: Vice President and General Counsel

# ANNEX A

# EXERCISE FORMS

# TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THE ATTACHED WARRANT AGREEMENT OF

DISCOVERY LABORATORIES, INC.

## SUBSCRIPTION

The undersigned,, pursuant to foregoing Warrant Agreement, hereby elects to exercise so agreeing to subscribe for and purchase shares") of Common Stock, par value \$.001 per share, of Inc. (the "Company"), and hereby makes payment of \$ official bank check or wire transfer of immediately available order of the Company in payment of the exercise price	uch Warrant Agreement by hares (the "Warrant Discovery Laboratories, by certified or lable funds payable to
The undersigned acknowledges that the sale, transfer hypothecation of the Warrant Shares to be issued upon exe Agreement is subject to the terms and conditions of the Wardersigned further acknowledges that the sale, transfer, hypothecation of the Warrant Shares to be issued upon exe Agreement is subject to the terms and conditions continue Warrant Agreement.	ercise of this Warrant Warrant Agreement. The , assignment or ercise of the Warrant
Dated: Signature:	
Address:	

# ASSIGNMENT

	the foregoing Warrant Agreement and irrevocably constitute and appoint ansfer said Warrant Agreement on the
books of Discovery Laboratories, Inc. (1	the "Company").
Dated:	Signature:
	Address:

# PARTIAL ASSIGNMENT

unto the rig Common Stock, par value \$.001 per share	ng Warrant Agreement, and a proportionate rights evidenced thereby, and does, attorney to transfer
Dated:	Signature:

\$8,500,000

December 10, 2001

FOR VALUE RECEIVED, DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), hereby promises to pay to the order of PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender"), in lawful money of the United States of America in immediately available funds, the lesser of (i) the principal sum of Eight Million, Five Hundred Thousand Dollars (\$8,500,000) and (ii) the aggregate unpaid principal amount of all Advances (as defined in the Loan Agreement referred to below) made by Lender to Borrower pursuant to the Loan Agreement (as defined below), together with interest accrued thereon. The interest shall accrue on the unpaid principal amount of each Advance at the rates and in the manner provided in the Loan Agreement. Payment of the principal amount of this Note and accrued interest on this Note shall be made at the times and in the manner provided in the Loan Agreement. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Loan Agreement.

Each Advance made by Lender to Borrower, and all payments made on account of the principal amount hereof, shall be recorded and endorsed by Lender on the grid attached hereto which is a part of this Note. Failure to so record and endorse such Advances and payments, however, shall not affect Borrower's obligations in respect of such Advances.

This Promissory Note is the Note referenced in the Loan Agreement between Borrower and Lender dated as of the date of this Note (as same may be amended from time to time, the "Loan Agreement"), and is entitled to the benefits of the Loan Agreement. The Loan Agreement, among other things, (i) provides for the making of certain Advances by Lender to Borrower from time to time, the principal amount of each such Advance being a principal amount evidenced by this Note, and (ii) provides that this Note is secured by, and Borrower has granted a security interest in, certain of its assets as set forth in that certain Security Agreement between Borrower and Lender dated as of the same date as this Note.

In case an Event of Default shall occur and be continuing and not cured prior to the expiration of any applicable cure or grace periods set forth in the Loan Agreement, the unpaid principal amount of, and accrued interest on, this Note may be declared to be due and payable in the manner and with the effect provided in the Loan Agreement.

Borrower hereby waives presentment, demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance and enforcement of this Note.

This Note is subject to early termination as set forth in the Loan Agreement. This Note may be voluntarily prepaid, in whole or in part, on the terms and conditions set forth in the Loan Agreement. Provided that no Advances or accrued interest are outstanding and have irrevocably been paid in full and the Commitment shall have expired or been terminated in accordance with

the terms of the Loan Agreement, the Lender shall, at the request of Borrower, promptly, and in no event later than ten (10) Business Days after notice from Borrower, cancel and return this Note to Borrower.

This Note shall be governed by and construed in accordance with the law of the State of Delaware without regard to the conflicts of law rules of such state.

This Note may not be assigned by Lender except to an Affiliate of Lender which agrees in an enforceable written instrument to be bound by all the terms and conditions of this Note as if it were Lender, which instrument shall be delivered a reasonably practicable time prior to such assignment.

Lender and Borrower agree that disputes relating to this Note shall be subject to the provisions of the Loan Agreement entitled "Internal Review" and "Arbitration" set forth in Sections 7.15 and 7.16 thereof, respectively.

BORROWER:

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

Name: David L. Lopez, Esq.

Title: Vice President, Legal Counsel

2

# ADVANCES AND PAYMENTS OF PRINCIPAL

	Amount	Amount of Principal Paid	Unpaid	Notation
Date	of Advance	or Prepaid	Principal Balance	Made By

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by [\*\*\*], have been separately filed with the Securities and Exchange Commission.

## COMMERCIALIZATION AGREEMENT

AMONG

## DISCOVERY LABORATORIES, INC.

and

## QUINTILES TRANSNATIONAL CORPORATION

## TABLE OF CONTENTS

	PAGE
ARTICLE 1	SERVICES OVERVIEW; QUINTILES EXCLUSIVITY1
1.1	Definitions1
1.2	Overview; Discovery Engagement of Quintiles1
1.3	Quintiles Exclusive Rights1
1.4	Retained Rights by Discovery1
ARTICLE 2	COMMITTEES
2.1	Joint Commercialization Committee ("JCC")2
2.1.1	Formation; Purposes and Principles2
2.1.2	Membership2
2.1.3	Meetings3
2.2	Agendas and Minutes for the JCC3
2.3	No Authority to Modify Agreement3
ARTICLE 3	MARKETING PLAN; DETERMINATION OF FULLY LOADED COST4
3.1	Marketing Plan4
3.2	Plan Contents4
3.3	Determination of Fully Loaded Cost4
3.3.1	Baseline for Fully Loaded Cost of Sales Force5
ARTICLE 4	QUINTILES RESPONSIBILITIES5
4.1	Covenant to Operate under the Agreement; General Diligence Requirement5
4.2	Marketing Services5
4.2.1	Marketing Representative5
4.3	Hiring Sales Force5
4.4	Fully Dedicated or Syndicated Sales Force6
4.5	Training Requirements6
4.6	Quintiles Responsibilities6
4.7	Records and Reports Regarding Promotional Activities7
4.8	Performance Audits7
ARTICLE 5	DISCOVERY'S RESPONSIBILITIES AND OBLIGATIONS7

Page	
5.1 Regulatory Affairs7	5.1
5.2 Minimum Pre-Launch Marketing Commitment7	5.2
5.3 Minimum Sales Force Expenditure7	5.3
5.4 Obligation to Provide Samples8	5.4
5.5 Sales and Distribution8	5.5
5.5.1 Pricing8	5.5.1
5.5.2 Booking Sales; Distribution8	5.5.2
5.5.3 Product Returns8	5.5.3
5.6 Discovery Responsibilites8	5.6
RTICLE 6 TRAINING; ADVERTISING AND PROMOTIONAL MATERIALS8	ARTICLE 6
6.1 Training Programs8	6.1
6.1.1 Content8	6.1.3
6.1.2 Cost9	6.1.2
6.2 Advertising and Promotional Materials9	6.2
6.2.1 Creation and Use9	6.2.1
6.2.2 Ownership; FDA Approval9	6.2.2
6.2.3 Discovery Logos9	6.2.3
RTICLE 7 REGULATORY ISSUES AND COMPLAINTS9	ARTICLE 7
7.1 Ownership of Regulatory Filings and Compliance9	7.1
7.2 Communication with the FDA and Other Regulatory Agencies10	7.2
7.3 New Developments Relating to Product10	7.3
7.4 Product Recalls10	7.4
7.5 Adverse Event Reporting Procedures10	7.5
7.6 Product Inquiries; Complaints10	7.6
7.7 Database of Clinical Trial Data11	7.7
RTICLE 8 ACCOUNTING; INVOICING AND PAYMENT11	ARTICLE 8
8.1 Accounting11	8.1
8.2 Payment Schedule11	8.2

		Page
	8.3	Payment of Invoices11
	8.3.1	Wiring Instructions11
	8.4	Penalty for Late Payment11
	8.5	Record Keeping and Financial Audits11
ARTICLE	9	REPRESENTATIVES AND COVENANTS12
	9.1	Mutual Authority12
	9.1.1	Corporate Power12
	9.1.2	Due Authorization12
	9.1.3	Binding Agreement12
	9.1.4	Grant of Rights; Maintenance of Agreements12
	9.1.5	Validity13
	9.2	Conformance with Laws13
	9.3	Rights in Product
	9.4	Record Maintenance
	9.5	Firewall14
	9.6	No Use fo Names or Trademarks14
	9.7	NDA Filing14
	9.8	Independent Contractor14
ARTICLE	10	CONFIDENTIALITY14
	10.1	Confidential Information14
	10.2	Ownership of Data; No License14
	10.3	Survival15
ARTICLE	11	INDEMNIFICATION15
	11.1	Indemnification by Discovery15
	11.2	Indemnification by Quintiles15
	11.3	Procedure15
	11.4	No Consequential Damages16
	11.5	Discovery Responsibility for Product Description16

	Page
11.6	Insurance
ARTICLE 12	TERM AND TERMINATION
12.1	Term16
12.2	Renewal16
12.3	Material Breach16
12.4	No Product Launch17
12.5	Bankruptcy17
12.6	Accrued Rights
12.7	Right to Receive Data18
12.8	Survival
ARTICLE 13	SALES FORCE CONVERSION
13.1	Right to Convert Sales Force
13.2	Transition Plan
13.3	Discovery Determination
13.4	Proprietary Information18
ARTICLE 14	DISPUTE RESOLUTION
14.1	Disputes
14.2	Governing Law19
ARTICLE 15	MISCELLANEOUS
15.1	Return of Materials19
15.2	Nonsolicitation of Employees
15.3	Entire Agreement; Amendment
15.4	Force Majeure20
15.5	Notices
15.6	Consents Not Unreasonably Witheld or Delayed21
15.7	Maintenance of Records21
15.8	United States Dollars21
15.9	No Strict Construction21

	'	Page
15.10	Assignment	21
15.11	Performance by Affiliates	22
15.12	Counterparts	22
15.13	Further Actions	22
15.14	Severability	22
15.15	Ambiguities	22
15.16	Headings	22
15.18	No waiver	22

DEFINITIONSA-1	
EXHIBIT B MARKETING PLAN OUTLINEB-1	
SCHEDULE I QUINTILES RESPONSIBILITIESSI-1	
SCHEDULE II DISCOVERY RESPONSIBILITIES & OBLIGATIONS, DISCOVERY SALES PROJECTSII-1	
SCHEDULE III ROLE DEFINITIONSSIII-1	

#### COMMERCIALIZATION AGREEMENT

THIS Commercialization Agreement (the "Agreement") is made effective as of the 10th day of December, 2001 (the "Effective Date"), by and between Discovery Laboratories, Inc., a corporation organized and existing under the laws of Delaware, having its principal place of business at 350 South Main Street, Suite 307 Doylestown, PA 18901-4874 ("Discovery"), and Quintiles Transnational Corp., a corporation organized and existing under the laws of North Carolina, with its principal place of business at 4709 Creekstone Drive, Suite 200, Durham, NC 27703 ("Quintiles"), each on behalf of itself and its Affiliates. Discovery and Quintiles are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

In consideration of the following covenants, promises and obligations, Discovery and Quintiles agree as follows.

## ARTICLE 1

#### SERVICES OVERVIEW; QUINTILES EXCLUSIVITY

- 1.1 Definitions. Capitalized terms used but not defined in the text of this Agreement shall have the meanings ascribed to them on Exhibit A hereto.
- 1.2 Overview; Discovery Engagement of Quintiles. Pursuant to this Agreement, and subject to the terms and conditions of, the Parties shall collaborate to develop and sustain a market for and promote Surfaxin(R) (the "Product", as further defined on Exhibit A) in the Territory. Subject to the terms and conditions of this Agreement, Discovery shall engage Quintiles and/or Quintiles Affiliates to provide (i) pre- and post-launch marketing activities ("Marketing Services") and (ii) the recruitment, deployment and management of a dedicated Sales Force ("Sales Force Services" and, together with any Marketing Services, "Services") for the Product in the Territory, on a preferred basis all as provided herein. In recognition of the various undertakings provided to Discovery herein and conditioned upon the performance of the payment obligations of PharmaBio Development, Inc. ("PharmaBio") as set forth in the (X) Investment and Commission Agreement (herein so called) and (Y) Loan Agreement (herein so called) between Discovery and PharmaBio, as appropriate, executed on the date hereof, Discovery shall pay Quintiles the compensation as set forth herein. While the Parties have allocated their respective responsibilities under this Agreement, the Parties intend this program to be broadly collaborative, and seek to achieve consensus-based decision making to the extent practical, with the common objective of maximizing the short-term and long-term commercial success of the Product in the Territory, subject to the terms and conditions of this Agreement. The Parties further intend to consider appropriate commercialization constructs with respect to jointly commercializing other neonatal products and the Product for other indications.
- 1.3 Quintiles Exclusive Rights. Subject to the terms and conditions of this Agreement, during the Term, Quintiles (either itself or through an Affiliate) shall have the exclusive right to provide Sales Force Services for the Product in the Territory. Except as otherwise provided herein, Quintiles shall not have any rights with respect to the Product inside or outside of the Territory.

1.4 Retained Rights by Discovery. Except as otherwise expressly provided in Section 1.3, Discovery shall retain all right, title and interest in and to the Product including, but not limited to, owning all clinical trial data and designs, protocols, regulatory filings, applications, and approvals for the Product and data in support thereof, and all manufacturing, distribution of finished products to designated third party distributor, patent, copyright, trade secret and trademark rights relating to the Product. Discovery shall be responsible for conducting all activities for clinical development of the Product. No license is granted to Quintiles hereunder, either directly or by implication. Quintiles acknowledges that any study sponsored by or under the direction of Discovery is a proprietary program of Discovery, containing trademarks, trade secrets and other intellectual property of Discovery, whether or not such rights are utilized in the marketing, promotion or sale of the Product.

#### ARTICLE 2

## COMMITTEES

- 2.1 Joint Commercialization Committee ("JCC").
- 2.1.1 Formation; Purposes and Principles. The JCC shall have overall responsibility for the success of the matters related to the Product in the Territory as established by this Agreement, including without limitation: (i) to review and approve the pre- and post-launch Marketing Plan as well as any other matters required for the sales and promotion of the Product in the Territory, except to the extent that certain matters are solely the responsibility of a single Party under this Agreement; (ii) to determine the overall strategy for marketing, promotion and sales of the Product in the Territory; (iii) to advise, provide input and determine strategy for future clinical and/or marketing studies; (iv) to plan and coordinate the Parties' activities hereunder related to sales and marketing of the Product in the Territory; (v) to adopt and approve plans and budgets for the Services under this Agreement, including the Marketing Plan, consistent with the maximization of short-term and long-term profits derived from the sale of the Product in the Territory and any other activities related to sales and marketing of the Product in the Territory that the JCC deems appropriate to achieve the Parties' objectives under this Agreement; (vi) to request the creation of sales, pricing, and financial reports pertaining to pre- and post-launch Services and other marketing activities that may be provided by third parties, and to review such reports in preparation for making recommendations; (vii) facilitate the flow of information among the Parties, including coordinating sales activity with manufacturing schedules and distribution; and (viii) to promptly resolve disputes of the Parties, subject to Article 14.
- 2.1.2 Membership. The JCC will be comprised of an equal number of Discovery and Quintiles representatives, not exceeding three representatives of each Party unless otherwise mutually agreed. The JCC shall be chaired by one of the Discovery representatives. The representatives of Discovery shall collectively be entitled to 1 vote and the representatives of Quintiles shall collectively be entitled to 1 vote. The JCC shall to the extent practicable seek to operate by consensus, provided that Discovery (through its chairperson) will have the tie-breaking vote on all JCC decisions and further provided, however, that Discovery shall not be entitled to use such tie-breaking vote to unilaterally amend the Agreement or make decisions materially impacting

the [\*\*\*] pursuant to Article 3. To the extent the JCC is not unanimous with respect to any of the matters set forth in the preceding sentence, the process outlined in Section 14 of this Agreement shall be followed. Either Party may appoint, substitute or replace members of the JCC to serve as their representatives upon notice to the other Party. The Parties shall appoint the initial members of the JCC within twenty (20) days after the Effective Date.

- 2.1.3 Meetings. The JCC shall meet in person, by video or by teleconference (as mutually agreed by the Parties from time to time) on a quarterly basis or more frequently as may be agreed upon, to exercise its responsibilities as set forth in Section 2.1.1 of this Agreement, and to review the progress of the Parties in performing the functions and obligations under this Agreement. Each Party will be responsible for its own travel and related costs to attend and host JCC meetings. Location of meetings shall alternate between Discovery headquarters in Doylestown and Quintiles headquarters in Research Triangle Park, or at such other locations as may be mutually agreed by the Parties. In order for a meeting of the JCC to be convened, such meeting must include at least one (1) committee member of each Party and, provided this condition is met, an unanimous action taken at such meeting shall have been duly and validly taken by the JCC. The first meeting of the JCC shall be convened within [\*\*\*] from the execution of this Agreement. An immediate task for the JCC shall be to set forth an initial [\*\*\*] plan including the setting of a deadline for the development of the Marketing Plan.
- 2.2 Agendas and Minutes for the JCC. Unless otherwise decided by the JCC, each Party will use reasonable efforts to disclose to the chair all proposed agenda items along with appropriate background or supporting information at least twenty (20) working days in advance of a JCC meeting. The chair will use reasonable efforts to will present an agenda with appropriate background or supporting information at least ten (10) working days in advance of a JCC meeting. After each meeting of the JCC, the Party whose turn it was hosting such meeting will prepare, within ten (10) working days after each meeting (whether held in person, by video or by telecommunication), the minutes reporting in reasonable detail the actions taken or to be taken by the JCC, or its designees, the attendees, the status of goals and achievements as well as issues requiring resolution, and resolutions of previously reported issues, which minutes shall set forth all pertinent information presented during the meeting in form and content reasonably acceptable to the other Party and shall be signed by one of the JCC representatives from each of the Parties.
- 2.3 No Authority to Modify Agreement. The JCC shall have no authority to amend or waive compliance with the terms and conditions of this Agreement, or to approve actions of the Parties which are inconsistent with this Agreement. Any such amendments and waivers or actions shall be implemented by means of Section 15.3.

## MARKETING PLAN; DETERMINATION OF FULLY LOADED COST

- 3.1 Marketing Plan. The principal mechanism by which the Parties coordinate their sales and marketing activities will be a Marketing Plan, to be prepared and periodically updated as set forth below. The Parties shall take preparatory steps with respect to the Marketing Plan in accordance with Section 2.1.3 but in any event the Marketing Plan shall be complete within the time set forth in Section 2.1.3, at which time the JCC shall submit the Marketing Plan to the respective Chief Executive Officers of the Parties (or their designees). In preparation for submission thereof, a draft Marketing Plan shall be prepared by members of the JCC or its designees, and submitted to the Chief Executive Officers for approval. The initial Marketing Plan will cover the year 2002 through the first year following Product Launch. Periodically thereafter, but no less frequently than annually (according to a schedule to be established by the JCC), the JCC shall be responsible for causing the preparation or updating of the Marketing Plan and submitting to the Chief Executive Officers for approval. Each Marketing Plan shall include at least a two (2) year projection of Product plans and budgets.
- 3.2 Plan Contents. Each Marketing Plan shall include a review of the marketplace, marketing objectives, strategies, and supporting tactics (with respective costs, timing, and responsibilities), clinical support plans, marketing study plans for future clinical and/or marketing studies, Sales Force effort, pricing, inventory requirements and distribution plans for the Product, together with sales, revenue and expense forecasts for Product sales in the Territory. The content of the Marketing Plan shall be determined by the JCC, but shall generally be in a form consistent with the outline attached hereto as Exhibit B, and shall include among other items the overall level of anticipated field sales resource commitments. All budgets contained in the Marketing Plan shall be based on estimates of the Quintiles Fully Loaded costs and associated pass-through expenses of the component services contained in the Marketing Plan.
- 3.3 Determination of Fully Loaded Cost. Quintiles under this Agreement shall be paid for by Discovery on the basis of the "Fully Loaded Cost" of such Services. Fully Loaded Cost means the usual and customary fee charged by Quintiles (or the Quintiles Affiliate, as the case may be) to Third Parties under a fee for service arrangement for the type of services rendered by it pursuant to this Agreement (such fee to be based on services of comparable volume and comparable quality), inclusive of the service provider's customary profit margin for such volume and quality of service. Fully Loaded Cost shall be adjusted on an annual basis for increases or decreases caused by cost of living adjustments, merit salary increases and similar financial adjustments necessary to maintain continuity of the personnel and resource commitments or as otherwise appropriate. Prior to Quintiles providing Marketing Services or Sales Force Services, the JCC shall execute a work order in form and substance satisfactory to the Parties (the "Work Order") setting forth the then current Fully Loaded Cost of such. The JCC shall update such Work Order as needed to reflect changes in the services being provided and/or changes in the usual and customary fees charged by Quintiles and Quintiles Affiliates. The Parties (through the JCC) shall indicate their agreement in advance regarding any new or revised type or volume of services, or changes to the pricing of such services by executing an appropriate change order.

3.3.1 Sales Force Services. In accordance with Section 4.3, Schedules I and II, and as otherwise appropriate in the circumstances, Quintiles will provide to Discovery a Sales Force, at the Fully Loaded Cost, to commence in a manner consistent with the then most currently approved version of the Marketing Plan, consisting of such number of Sales Representatives and management and administrative support as the JCC determines is in the best interest of the Product. The post-Launch term of the Quintiles Sales Force Services shall be for 7 years. The JCC may advance the start of the Sales Force or amend the size of the Sales Force as necessary. In the event a Syndicated Sales Force (as hereinafter defined) is recommended by the JCC, pursuant to Section 4.4 of this Agreement, the Fully Loaded Cost shall be determined by Quintiles, and except as otherwise provided herein, Discovery shall be responsible for such Fully Loaded Cost, except for such portions of the Fully Loaded Cost as may be contractually undertaken by one or more third parties, with the consent of Quintiles, which consent shall not be unreasonably withheld.

## ARTICLE 4

#### QUINTILES RESPONSIBILITIES

- 4.1 Covenant to Operate under the Agreement; General Diligence Requirement. Quintiles shall use its commercial best efforts to market and sell the Product in the Territory in accordance with the Marketing Plan, the Promotional Materials, this Agreement and all applicable laws, rules and regulations. Except as expressly set forth in this Agreement, the criteria for Quintiles performance shall be consistent with the Quintiles standards for sales and marketing projects of similar size and scope and shall be according to performance metrics to be established and monitored by the JCC.
- 4.2 Marketing Services. Quintiles shall provide all Marketing Services on a fee-for-service basis, charging the Fully Loaded Cost. Pre- and post-launch Marketing Services shall be included in the Marketing Plan and shall include the Fully Loaded Cost of a Product Manager as defined in Section 4.2.1. The fees and expenses for Marketing Services may be paid by Discovery through advances from PharmaBio or otherwise.
- 4.2.1 Product Manager. An initial activity of the JCC will be the approval of a Quintiles Personnel as the primary product manager for the Product (the "Product Manager") to coordinate and/or commence Marketing Services and other marketing activities, including participation with and supporting the JCC in the design of the pre- and post-launch Marketing Plan. Quintiles will recommend for Discovery's approval a qualified employee for this role, who shall be assigned full-time, unless otherwise agreed by the JCC. The Product Manager shall report to a Quintiles Personnel of suitable experience and stature within Quintiles and shall aggressively drive marketing and related pre- and post-launch recommendations. As appropriate, the Product Manager will recommend to the JCC when additional resources are needed, on a dedicated or non-dedicated basis, to optimize marketing results. As a component of pre-launch marketing activities, the Product Manager will recommend to the JCC solutions on a variety of ancillary relationships, including, but not limited to distribution relationships. The Marketing Plan shall include the costs related to the services of the Product Manager at his or her usual and customary hourly rate and the reasonable expenses of the Product

- 4.3 Hiring Sales Force. As part of post-launch Marketing Services, Quintiles shall hire, train and maintain the Sales Force for promotion of the Product in the Territory on the terms and conditions of this Agreement, which shall be completed at least one (1) month in advance of the date of the expected Launch (as communicated by the JCC to Quintiles in writing at least four (4) months in advance of the expected Launch). The hiring standards for the members of the Sales Force shall be established by the JCC. The Quintiles Sales Force(s) size will be determined by the JCC in accordance with the investment recommended by the JCC as part of the Marketing Plan and at a minimum shall meet the requirements of the Investment and Commission Agreement, including the Minimum Sales Force Level, as defined therein. By unanimous agreement, the JCC may establish a Sales Force Commencement Date different than as set forth herein.
- 4.4 Fully Dedicated or Syndicated Sales Force. During the Term, the primary activity of the Sales Force shall be the marketing and promotion of the Product in the Territory on a P1 basis, unless otherwise approved in advance by the JCC. The Sales Force shall be composed of full-time employees of Quintiles. Quintiles may use the P2 and/or P3 positions to promote non-conflicting compounds or devices, subject to Discovery consent, which consent shall not be unreasonably withheld. Discovery shall have the first option to place Discovery's non-conflicting products, or non-conflicting products Discovery identifies or acquires, in the P2 and P3 positions as the positions may become available during the term of this Agreement. In addition, Discovery shall have the right to take over any P2 or P3 services provided by Quintiles to a third party on 120 days notice to Quintiles. All P2 and P3 services shall be provided to Discovery on a fee for service basis based on the Fully Loaded Costs for such services. Any syndicated team (a "Syndicated Sales Force"), will be branded consistent with the Product being promoted in the P1 position and any promotional materials with regard to the Syndicated Sales Force (business cards, etc.) shall be approved by the JCC after giving due consideration to the interests of the P2 or P3 third party partner, such approval not to be unreasonable withheld.
- 4.5 Training Requirements. Quintiles shall train all Quintiles Personnel in accordance with Article 6 hereof.
- 4.6 Quintiles Responsibilities. Without limitation a partial list of responsibilities that shall be performed by Quintiles in providing Sales Force Services are set forth on Schedule I to this Agreement.
- 4.7 Records and Reports Regarding Promotional Activities. Quintiles shall promptly (and in any event as soon as it is generally available within the Quintiles organization) provide to Discovery such information regarding ongoing sales and marketing activities as relate to the plans and budgets hereunder as Discovery may reasonably request and which are reasonably available to Quintiles. Additionally, Quintiles will keep complete and accurate records of all presentations made by the Sales Force in accordance with Quintiles's customary call reporting procedures (including names of physicians, dates of presentation and general response to such presentations) as well as other activities carried out pursuant to the Marketing Plan. Quintiles will make all such records available to Discovery during regular business hours and upon reasonable notice, and will, within fifteen (15) days of the end of each month, provide Discovery a monthly report on sales force activity. Quintiles will maintain such records for three (3) years following the period to which they

relate. The record-keeping and access requirements of this Section 4.7 shall survive the termination of this Agreement for a two (2) year period.

4.8 Performance Audits. Discovery shall have the right to audit Quintiles' performance of obligations as set forth in this Article 4, including other provisions as described in the Schedules attached hereto (generally describing the activities of the Parties) for the purpose of evaluating and monitoring conformance with the terms and conditions of this Agreement. Such audits shall occur during regular business hours and upon reasonable notice, shall not unduly interfere with Quintiles activities, and shall be conducted at Discovery's sole expense. In the event an outside auditor is hired to conduct an audit pursuant to this Section 4.8, such auditor shall be reasonably acceptable to Quintiles and expressly subject to the same confidentiality provisions as those that apply to the Parties hereunder.

#### ARTICLE 5

## DISCOVERY'S RESPONSIBILITIES AND OBLIGATIONS

- 5.1 Regulatory Affairs. Except as otherwise set forth therein, Discovery shall have the responsibilities for regulatory affairs set forth in Article 7, and shall keep the JCC informed generally on the status and conduct of all clinical development activities related to the Product in the Territory. Discovery shall inform Quintiles of its estimated date of Product Launch, and in particular shall provide such date for purposes of Quintiles establishment of the Sales Force under Section 4.3.
- 5.2 Minimum Pre-launch Marketing Services Commitment. Discovery shall spend a minimum of [\*\*\*] of the cost of all pre-Launch Marketing Services (the aggregate amount of pre-Launch Marketing Services to be determined by the JCC) on Services provided by Quintiles. The fees and expenses for such pre-Launch Marketing Services may be paid by Discovery through advances from PharmaBio or otherwise.
- 5.3 Obligation to Provide Samples. Discovery will provide to Quintiles for distribution the quantity and configuration of Samples as determined appropriate by the JCC to support the Sales Force Services, consistent with the Marketing Plan and forecasts. Distribution of such Samples shall be carried out by Quintiles consistent with the Marketing Plan and as otherwise set forth on Schedule I. Except as set forth in the next sentence, the costs related to such distribution hereunder shall be considered to be "Commercialization Expenses" as defined in the Investment and Commission Agreement and, as such, may be funded by Discovery with advances from PharmaBio in accordance therewith or otherwise. Discovery shall be responsible for the manufacture, packaging and distribution of Samples to the Sales Force and shall have primary responsibility for compliance with the requirements of the FDA Final Rule implementing the PDMA (21 CFR Parts 203 & 205), including, but not limited to (a) a sample accountability and tracking system for use by the Sales Representatives; (b) verification of licensed practitioners; (c) annual physical inventories and reconciliation reports; (d) monitoring and investigation of discrepancies, significant losses, thefts and falsification of sample records; (e) notification and reporting to FDA; (f) a sample distribution

security and audit system, including conducting random and for cause audits of sales representatives by personnel independent of the sales force; and (g) training the Sales Force regarding the foregoing. Discovery and Quintiles shall cooperate in connection with PDMA compliance investigations and audits. Discovery will provide to Quintiles for review and comment, a copy of any PDMA compliance report in connection with the Sales Force, prior to filing with the FDA. Discovery will provide Innovex with results of annual Sales Representative sample inventories. Discovery shall be responsible for the cost of independent random audits of Sales Representatives, to be coordinated by Quintiles.

### 5.5 Sales and Distribution.

- 5.5.1 Pricing. Discovery, with the advice of the JCC, shall set all prices and commercial terms for the sale of the Product in the Territory.
- 5.5.2 Booking Sales; Distribution. Discovery shall be responsible for booking sales, fulfilling orders, and shall warehouse and distribute the Product and perform all related services.
- 5.5.3 Product Returns. Discovery shall be responsible for handling Product returns. The Quintiles Sales Force shall provide assistance as reasonably requested by Discovery, to the extent consistent with the normal activities of pharmaceutical sales personnel. Product returns shall promptly be shipped to the facility responsible for shipment of such Product lot or such other location as may be designated by Discovery in writing.
- 5.6 Additional Discovery Responsibilities. A partial list of certain additional responsibilities of Discovery responsibilities are set forth on Schedule II attached to this Agreement.
- 5.7 Preferred Provider Relationship. Discovery hereby grants to Quintiles the first and preferred opportunity to negotiate with Discovery to provide (a) clinical trial development and/or (b) commercialization services of the type commonly provided by the Quintiles (or any or its Affiliates), whether related to the Product or otherwise, that Discovery has, in its sole discretion, determined to outsource for the period beginning on the date hereof and ending five years following the Funding Date; provided that, as determined in Discovery's sole discretion: (i) the applicable services fall with the areas of recognized expertise of the Quintiles (or its Affiliates), (ii) the Quintiles (or its Affiliates) provides such services at competitive rates and makes its proposal on a competitive time schedule, and (iii) the Quintiles (or its Affiliates) expressly agrees to provide such services to meet Discovery's timeline. Without limiting the foregoing, Discovery agrees to keep Quintiles informed of the development of Surfaxin(R) in its present formulation for the ARDS treatment indication and Discovery shall outsource such work to Quintiles (or its Affiliates) with regard to the ARDS indication that Quintiles (or its Affiliates) is capable of performing so long as Quintiles (or its Affiliates) services can be performed in conformance with subsections (i), (ii) and (iii) above.

## TRAINING; ADVERTISING AND PROMOTIONAL MATERIALS

#### 6.1 Training Programs.

- 6.1.1 Content. Quintiles will develop, subject to JCC approval (not to be unreasonably withheld), initial and ongoing training programs for the Sales Force during the Term. Each member of the Sales Force shall be required to successfully complete such training program before providing services under this Agreement. The Parties shall mutually agree to a minimum training standard and pass rate, to be monitored by the JCC. Quintiles shall maintain records of such training for each individual which shall be maintained by Quintiles in accordance with Section 4.7 and made available to Discovery in accordance with applicable law. Quintiles agrees to utilize such training programs on an ongoing basis. Initial training shall be carried out at a time which is set by the JCC and which is prior to but reasonably near the date on which Product Launch is expected. As additional Sales Representatives are added under this Agreement, training will be given to groups of the newly selected Sales Representatives, provided that the training of such representatives is intended to occur as soon as practicable. In addition to Product and selling skills training, training programs shall include requirements of the Food, Drug and Cosmetic Act, Medicare/Medicaid Anti-Fraud and Abuse Act, and other applicable laws, rules, regulations and policies.
  - 6.1.2 Cost. The cost of developing and delivering the training to the Sales Force shall be borne by Discovery. Quintiles shall charge Discovery its Fully Loaded Cost for training services as a post-Launch Marketing Service.
  - 6.2 Advertising and Promotional Materials.
  - 6.2.1 Creation and Use. Discovery shall be responsible for the development of all Promotional Materials. Such development shall be part of and consistent with the Marketing Plan and budgets approved by the JCC. The Quintiles Sales Force shall disseminate only Promotional Materials provided by Discovery, for use by the Sales Force. Discovery will engage Quintiles or Quintiles Affiliates to assist with the development and creation of Promotional Materials.
  - 6.2.2 Ownership; FDA Approval. Discovery shall own all rights to, and title and interest in, the Promotional Material. The final content of all Promotional Materials and Product-related training materials shall be the legal responsibility of Discovery, including, but not limited to, FDA approval thereof if such approval is required.
  - 6.2.3 Discovery Logos. All written or visual materials related to the Product shall display the Discovery logos and Discovery shall be presented as the sole owner of the Product, except as required by law.

## REGULATORY ISSUES AND COMPLAINTS

- 7.1 Ownership of Regulatory Filings and Compliance. Discovery will retain exclusive right, ownership, authority and responsibility for regulatory filings, compliance with all regulatory requirements and maintenance of all government agency contacts relating to the Product; the reporting of any adverse drug reactions to the FDA (to the extent applicable and required by law or regulation); the filing of Promotional Materials with the FDA (to the extent applicable and required by law or regulation); the payment of Medicaid and other governmental rebates which in Discovery's sole judgment are due and owing; the pricing of the Product for each customer; and compliance with Medicaid best price law and the Department of Veterans Affairs Act. The development of each indication and formulation of the Product shall be determined solely by Discovery. Neither Party shall be responsible for actions of the other that are outside the scope of this Agreement or not in accordance with applicable law.
- 7.2 Communication with the FDA and Other Regulatory Agencies. Except as required by law, Quintiles shall not communicate with the Food & Drug Administration, Office of Inspector General, Health Care Financing Administration or any state agencies ("Regulatory Agencies") about anything relating to the Product, except through, or with the prior written consent of Discovery. If Quintiles is required by law to communicate directly with any Regulatory Agency or if Quintiles receives any communication from a Regulatory Agency with respect to the Product, promotion of the Product, Quintiles' performance under this Agreement or any matter or that could affect Quintiles' performance under this Agreement, Quintiles shall promptly notify Discovery in writing. Quintiles shall reasonably cooperate at Discovery's expense with Discovery in all proper respects in all regulatory matters relating to the Product, including but not limited to preparation for inspections of Discovery facilities and/or Quintiles facilities. Quintiles will provide Discovery with pertinent records in Quintiles' possession which may be necessary to implement any recall or any other corrective action mandated by a Regulatory Agency or implemented by Discovery, including but not limited to names and addresses for "Dear Doctor" letters.
- 7.3 New Developments Relating to the Product. Discovery will promptly inform Quintiles of the following information relating to the Product in the Territory: (i) new approved indications; (ii) new approved dosages or administration regimens; (iii) material new studies by the scientific community that Discovery becomes aware of which relate to the Product or a competitive product in its therapeutic class; and (iv) any changes in regulations affecting the Product or Discovery's obligations with respect to this Agreement. Quintiles will promptly inform Discovery of information relating to changes in regulations affecting Quintiles's obligations with respect to this Agreement. Based on such information, and subject to any federal, state or local laws and/or regulations, the Parties shall use commercially diligent efforts to maintain the training materials and Promotional Materials supplied to the Sales Force pursuant to this Agreement current with such new developments or information.
- 7.4 Product Recalls or Withdrawal. If either Party believes that a recall of any Product in the Territory is necessary, such Party shall immediately notify the other Party. Discovery shall retain sole authority and responsibility for determining whether a Product recall shall occur. Any

Product recall shall occur under the direction and control of Discovery, and Quintiles shall reasonably cooperate in carrying out any such recall or any regulatory matter, at Discovery's expense and with reasonable expedience. Discovery shall make available, at Quintiles' request, any records that Quintiles might reasonably require to assist Discovery in effecting any recall of the Product.

- 7.5 Adverse Event Reporting Procedures. Discovery shall be responsible for required reporting of adverse events and drug safety issues related to the use of the Product. Discovery shall advise Quintiles of its standard procedures for the reporting of adverse events, and the Quintiles Sales Force shall comply with such procedures. The Discovery procedures for the reporting of adverse events shall be included in the training program for the Quintiles Sales Force. Quintiles shall report to Discovery within twenty-four (24) hours any adverse events of which Quintiles becomes aware reported to it.
- 7.6 Product Inquiries; Complaints. Quintiles shall promptly notify Discovery of any complaint, inquiry or (in compliance with Section 7.5) adverse event relating to the Product in report form providing reasonable detail of such complaint, event or inquiry. Discovery shall maintain a unified record of all complaints it receives. Discovery shall be responsible for medical affairs services and shall respond to inquiries from physicians and health care providers. Discovery shall advise Quintiles of its procedures for handling such inquiries and the Quintiles Sales Force shall be trained by Quintiles on such procedures.
- 7.7 Database of Clinical Trial Data. Discovery shall own and maintain its own database of clinical trial data accumulated from all clinical trials of the Product and Discovery shall own and maintain a unified database of complaints and adverse drug event information for the Product and shall develop and utilize uniform report forms.

#### ARTICLE 8

#### ACCOUNTING; INVOICING AND PAYMENT

- 8.1 Accounting. Each Party agrees to calculate all costs and expenses hereunder using its standard accounting procedures, in accordance with accounting principles generally accepted in the United States, consistently applied, to the maximum extent practicable.
- 8.2 Payment Schedule. Except as may otherwise be expressly provided in a Work Order, Quintiles will invoice Discovery monthly for Quintiles's actual fees and pass-through Expenses for the preceding calendar month (each an "Invoice"). Upon termination or expiration of the Services, any fees or pass-through expenses incurred prior to such termination will be invoiced to Discovery.
- 8.3 Payment of Invoices. All Invoices are strictly net of any taxes imposed on services, and except as otherwise set forth in this Agreement, payment in full is due within thirty (30) days of the date of receipt of the Invoice and shall be made by wire transfer.
- 8.3.1 If the method of payment is by direct transfer to the Quintiles bank account, the wire transfer instructions are as follows:

Quintiles Transnational Corporation Accounting Number: ABA Number: 053 101 121 Branch Banking & Trust Co., Raleigh, NC

Quintiles's Federal Employment ID Number is 56-1714315.

- 8.4 Penalty for Late Payment. Discovery and Quintiles agree that unless there is a bona fide dispute as to amounts payable hereunder, if payment is not made within 30 days of the due date of the invoice, interest shall accrue on a daily basis at the lesser of two percent (2%) above the Prime Rate as announced periodically by First Union National Bank (or its successor) or the maximum rate permitted by law on any amount overdue from the date payment became due until payment is made in full. In any event, such interest penalty shall only be assessed for undisputed and unpaid amounts.
- 8.5 Record-Keeping and Financial Audits. Upon the written request (and expense) of either Party, the other Party, but not more than once in each calendar year, shall permit an independent certified public accountant appointed by such Party and reasonably acceptable to the other Party, accompanied by representatives of the financial department of such Party at reasonable times and upon reasonable notice, to examine only those records as may be necessary to determine compliance with this Agreement. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit discloses a variance of more than ten percent (10%) from the amount of the original report, royalty or payment calculation. In such case, the Party being audited shall bear the full cost of the performance of such audit. Auditors shall be expressly subject to the same confidentiality obligations as the Parties are to each other hereunder. This Section 8.5 shall survive for two (2) years after the termination of this Agreement.

#### ARTICLE 9

#### REPRESENTATIONS AND COVENANTS

- 9.1 Mutual Authority. Each Party represents and warrants to the other that:
- 9.1.1 Corporate Power. It is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.
- 9.1.2 Due Authorization. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.
- 9.1.3 Binding Agreement. This Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

- 9.1.4 Grant of Rights; Maintenance of Agreements. It has not, and will not during the term of this Agreement, grant any right to any Third Party which would conflict with the rights granted to the other Party hereunder or enter into any agreement which would impair its ability to perform its obligations under this Agreement. It has (or will have at the time performance is due) maintained and will maintain and keep in full force and effect all agreements necessary to perform its obligations hereunder.
- 9.1.5 Validity. It is aware of no action, suit or inquiry or investigation instituted by any governmental agency that questions or threatens the validity of this Agreement.
- 9.2 Conformance with Laws. Quintiles and Discovery agree to undertake all of their respective obligations under this Agreement in material conformance with all applicable local, state and federal laws and regulations, as amended, including, without limitation, the Federal Equal Employment Opportunity Act, the Fair Labor Standards Act, the Food Drug and Cosmetics Act, Section 1128B(b) of the Social Security Act, the, the Medicaid Prescription Rebate Act, the Veterans Health Care Act of 1992, and similar state laws. By entering into this Agreement, it is not the intent of the Parties to enter into any financial relationship or arrangement prohibited under state or federal fraud or abuse regulations, including, but not limited to Sec. 1128B(b) of the Social Security Act, and any regulations promulgated thereunder, nor do the Parties hereto have any belief that the relationship and compensation arrangement provided in this Agreement are prohibited by law or regulation. Neither Party shall assert against the other that the compensation arrangement provided in this Agreement is grounds for voiding the Agreement or rendering the Agreement unenforceable. If either Party is notified by a state or federal agency, or it is alleged in a qui tam proceeding, that performance of this Agreement is illegal, neither Party shall be obligated to continue such performance hereof to the extent such performance is an alleged violation of law. In such event, the Parties shall proceed as described in the final sentence of Section 15.14.
- 9.3 Rights in Product. As of the Effective Date, Discovery warrants and represents that it is not aware of any valid patent or trademark owned or controlled by anyone other than Discovery or its licensors or an Affiliate thereof which covers the Product and which would prevent Discovery from making, using, or selling the Product or would prevent Discovery or Quintiles from promoting or marketing the Product in the Territory. Discovery is not aware of any valid patents or trademarks owned by Third Parties that would be infringed by the promotion or sale of the Product in the Territory. Discovery is not pursuing any action against any Third Party that Discovery believes infringes its trademark, copyright or patent relating to the Product. There are no actions, suits, claims or proceedings pending against Discovery or any of its Affiliates in any court or before any agency in the Territory related to alleged patent, trademark, or copyright infringement in connection with the Product, and to the best of Discovery's knowledge, no such actions, suits, claims or proceedings have been threatened. During the term of this Agreement, Discovery will use commercially reasonable and diligent efforts not to diminish the rights granted to Quintiles herein, including without limitation by not committing or permitting any acts or omissions which would cause the material breach of any agreements between Discovery and Third Parties which provide for intellectual property rights applicable to the development, manufacture, use or sale of the Product in the Territory. As of the Effective Date, Discovery is in compliance in all material respects with any such agreements with Third Parties.

- 9.4 Record Maintenance. Quintiles will (i) maintain all necessary personnel and payroll records for Quintiles Sales Force and other Quintiles employees providing Marketing Services and Sales Force Services; (ii) compute their wages and withhold applicable Federal, State, and local taxes and Federal FICA payments; (iii) remit employee withholdings to the proper governmental authorities and make employer contributions for Federal FICA and Federal and State unemployment insurance payments; (iv) pay net wages and fringe benefits, if any, directly to its employees; and (v) provide for liability and Workers' Compensation insurance coverage.
- 9.5 Firewall. Quintiles represents and warrants that it shall maintain as confidential, shall keep separate and shall not share with other parts of the Quintiles organization (including any Affiliate of Quintiles) that are or may be engaged in the promotion and/or sales of a competing product, the material and information supplied and/or generated hereunder for use in accordance with this Agreement and the promotion and sale of the Product.
- 9.6 No Use of Names or Trademarks. Except as otherwise provided in this Agreement, neither Party will use the other Party's name in connection with any publication or promotion without the other Party's prior written consent. Nor shall either Party use the other Party's corporate or product logo or trademark in any manner without the other Party's prior written consent.
- 9.7 NDA Filing. Discovery agrees to continue to exercise diligent efforts to submit the NDA for the Product to the FDA and to reasonably diligently seek FDA approval for the Product, to the extent applicable. Upon the approval of either the MAS or the IRDS indication, Discovery shall continue to use commercially reasonable efforts to submit the NDA for the other indication to the FDA and to seek FDA approval of such.
- 9.8 Independent Contractors. For the purposes of this Agreement, the Parties hereto are independent contractors of each other, and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer and employee, licensee and sublicensee or joint venturers. Neither Party shall have the power or right to bind or obligate the other Party, nor shall either Party hold itself out as having such authority. No provision of this Agreement shall be deemed to create or imply any contract of employment between Discovery and any employee of Quintiles. All persons performing Services shall be employees of Quintiles, or subcontractors engaged by Quintiles with prior consent of Discovery, and shall not be entitled to any benefits applicable to employees of Discovery. Quintiles shall be responsible for management of all employer obligations in connection with Quintiles employees who perform the Services. Quintiles employees shall remain exclusively under the direct authority and control of Quintiles. The employer obligations of Quintiles shall include: (i) human resource issues, including establishment of employee policies, and administration of health and benefits plans, 401K plan, and other employee benefit plans; (ii) work performance and work behavior issues, including probationary period, periodic and annual appraisals, employee discipline and termination; (iii) administration of systems for time-keeping, payroll and employee expense reimbursement; (iv) day to day management of employment issues in connection with performance of the Services.

#### CONFIDENTIALITY

- 10.1 Confidential Information. Quintiles and Discovery agree that all information relating, directly or indirectly, to the Product, or the business affairs or finances of the other or Affiliates or of any suppliers, agents, distributors, licensees or customers of the other which comes into possession of Quintiles or Discovery under this Agreement shall be Confidential Information ("Confidential Information"). This Agreement and related documentation shall also be treated as Confidential Information. Quintiles agrees to hold Confidential Information in strict confidence and disclose it only on a need-to-know basis to Affiliates, subcontractors and employees who are under a written obligation to maintain the confidentiality of the information. Notwithstanding the foregoing, Confidential Information does not include, information:
- 10.1.1 which can be shown by written documentation to have been known by the recipient prior to its receipt from the other;
- 10.1.2 which is public or lawfully becomes generally available to the public through no fault of the recipient;
- 10.1.3 which is lawfully acquired from a Third Party without being made subject to an obligation of confidence by the Third Party provided such Third Party is not itself under a legal or contractual obligation to keep such information confidential;
- 10.1.4 which by mutual written agreement is released from a confidential status; or
- 10.1.5 which is required to be disclosed under any statutory, regulatory or judicial requirement, including, but not limited to, any filing with the Securities Exchange Commission and, in that event, confidentiality will be preserved and protected to the extent possible and; notice will be provided to the other Party a reasonable amount of time prior to any such disclosure and such other Party given a reasonable opportunity to contest or limit such disclosure.
- 10.2 Ownership of Data and Intellectual Property; No License. It is expressly agreed that neither Party transfers to the other Party by operation of this Agreement any patent right or license, copyright or other proprietary right. All data and information generated or derived by Quintiles as the result of Services performed by Quintiles under this Agreement shall be and remain the exclusive property of Discovery. Discovery acknowledges that Quintiles possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, computer technical expertise and software, and business practices, including, but not limited to the Quintiles Territory Management System (ITMS), which have been independently developed by Quintiles (collectively "Quintiles Property"). Discovery and Quintiles agree that any Quintiles Property or improvements thereto which are used, improved, modified or developed by Quintiles under or during the term of this Agreement are the sole and exclusive property of Quintiles.

- 10.3 Publicity. Except as otherwise required by applicable law or by obligations pursuant to any listing agreement with or rules of any securities exchange or automated quotation system, each party shall, and shall cause its respective Affiliates to, not, issue any press release or make any other public statement relating to, connected with or arising out of this Agreement or the matters contained herein without the other parties' prior written approval of the contents and the manner of presentation and publication thereof (which approval shall not be unreasonably withheld or delayed).
- 10.4 Survival. The obligations of Quintiles and Discovery under this Article 10 shall survive the termination or expiration of this Agreement for a period of five (5) years.

#### **INDEMNIFICATION**

- 11.1 Indemnification by Discovery. Discovery shall indemnify, defend, save, protect, and hold harmless Quintiles, its Affiliates, and its and their respective directors, officers, employees, and agents ("Quintiles Indemnitees") against any and all losses, claims, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses and court costs) (collectively, "Losses") resulting or arising from any Third Party claims, actions, proceedings, investigations or litigation relating to or arising from or in connection with: (i) the design, development, manufacture, sale, distribution or use of the Product; (ii) the breach by Discovery of any of its obligations under this Agreement; (iii) the negligent or wrongful acts or omissions of Discovery or any of its directors, officers, employees or agents; (iv) a violation of any law, rule or regulation by Discovery relating to this Agreement; (v) the Promotional Materials or any other materials referred to in Section 6.2; or (vi) the infringement or violation, or alleged infringement or violation, by Discovery or the Product of any patents or any copyrights, trademark, trade secret or other intellectual property rights of a third party. Notwithstanding the foregoing, Discovery shall not be required to indemnify Quintiles for any Losses to the extent they arise from (a) the negligent or willful misconduct of Quintiles or any of the Quintiles Indemnitees or (b) Quintiles's breach of its obligations under this Agreement.
- 11.2 Indemnification by Quintiles. Quintiles shall indemnify, defend, save, protect, and hold harmless Discovery, its Affiliates, and its and their respective directors, officers, employees, and agents (the "Discovery Indemnitees") against any and all Losses resulting or arising from any Third Party claims, actions, proceedings, investigations or litigation relating to or arising from or in connection with: (i) the marketing, promotion or sale of the Product by Quintiles in a manner which violates this Agreement; (ii) the breach by Quintiles of any of its obligations under this Agreement; (iii) the negligent or wrongful acts or omissions of Quintiles or any of its directors, officers, employees or agents; (iv) a violation of any law, rule or regulation by Quintiles relating to this Agreement; or (v) the representations or misrepresentations by Quintiles relating to the Product which were not consistent with the labeled claims or Promotional Material. Notwithstanding the foregoing, Quintiles shall not be required to indemnify Discovery for any Losses to the extent they arise from (a) the negligent or wrongful acts or omissions of Discovery or Discovery Indemnitees; (b) the breach by Discovery of its obligations under this Agreement; (c) a manufacturing or design defect of the Product; or (d) a strict liability claim related to the Product.

- 11.3 Procedure. The Party seeking indemnification hereunder (the "Indemnified Party") shall (a) promptly notify the Party obligated to indemnify (the "Indemnifying Party") of any Losses for which the Indemnified Party seeks indemnification (provided that the failure to so notify shall not affect or reduce the Indemnifying Party's obligations hereunder, unless the Indemnifying Party's ability to defend against such Third Party claim, action, proceeding, investigation or litigation is materially prejudiced by such failure); (b) cooperate fully with Indemnifying Party and its legal representatives in the investigation of any matter that is the subject of indemnification; (c) permit the Indemnifying Party full control over the defense and settlement of any matter the subject of indemnification; and (d) not unreasonably withhold its approval of the settlement of any claim, liability or action by Indemnifying Party covered by this indemnification provision.
- 11.4 No Consequential Damages. Notwithstanding the Parties' rights and remedies in equity neither Party, nor its Affiliates or their respective directors, officers, employees or agents shall have any liability to the other for any special, incidental, indirect or consequential damages, including, but not limited to the loss of opportunity, use, revenue or profit, in connection with or arising out of this Agreement, or the Services performed by Quintiles hereunder, even if such damages were foreseeable.
- 11.5 Discovery Responsibility for Product Description. Quintiles shall not be liable to Discovery for claims or losses arising out of the statements or representations of the Quintiles Personnel with respect to the Product to the extent the statements or representations conform to the oral, written or printed statements or representations made to the Quintiles Personnel by Discovery with respect to the Product or contained in the Product labeling, Promotional Materials or other material referred to in Section 6.2, provided all such materials have been approved in advance in writing by Discovery.
- 11.6 Insurance. Quintiles and Discovery shall each, at its own cost and expense, obtain and maintain in full force and effect, the following insurance during the Term (and any subsequent renewals thereof): (i) worker's compensation insurance in accordance with the statutory requirements of each state in which the Services are to be performed; (ii) employer's liability insurance with a minimum limit of [\*\*\*]; (iii) comprehensive general liability insurance, including contractual liability and professional errors and omissions coverage, with a minimum limit of [\*\*\*], combined single limit per occurrence; and (iv) comprehensive auto liability, covering bodily injury and property damage, for owned, hired or non-owned automobiles with a minimum limit of [\*\*\*], combined single limit per occurrence. In addition, Discovery shall carry product liability insurance covering the Product in the Territory, in a minimum amount of [\*\*\*] per claim at all times following Launch. Each party shall provide the other party an original signed certificate of insurance evidencing all coverage herein required, within thirty (30) days after the effective date of this Agreement. The certificate must provide that thirty (30) days prior written notice of cancellation or material change in insurance coverage will be provided. The insurance obligations hereunder may be met by a program of self-insurance.

## TERM AND TERMINATION

- 12.1 Term. The Term of this Agreement will begin on the Effective Date and continue until the seventh anniversary of the Product Launch Date, unless the Agreement is terminated earlier, or renewed, in accordance with this Article 12 (together with all extension Terms as set forth in Section 12.2, the "Term").
- 12.2 Renewal. This Agreement will terminate at the end of the initial Term set forth in Article 12.1 unless the Parties agree in writing on terms to renew this Agreement at least 90 days prior to the end of such initial Term.
- 12.3 Material Breach. Either Party may terminate this Agreement by written notice at any time if the other Party defaults in the performance of any material obligations under this Agreement. In the event of such default, the Party declaring the default shall provide the defaulting Party with written notice setting forth the nature of the default, and the defaulting Party shall have thirty (30) days to cure the default. If the defaulting Party fails to cure the default within the 30-day periods, and provided the default is continuing, the other Party may terminate this Agreement by written notice to the defaulting Party, which notice shall be effective upon receipt.
- 12.4 No Product Launch. Either Party may terminate this Agreement (i) if Discovery has terminated development of the Product and has determined that it will market and launch neither the MAS or IRDS indication and provides Quintiles written notice of such, or (ii) if Launch of the Product for neither the IRDS or MAS indication occurs prior to [\*\*\*].
- 12.5 Bankruptcy. Either Party may terminate this Agreement by written notice to the other Party, if the other Party files a petition for bankruptcy, reorganization or arrangement under any state statute, or makes an assignment for the benefit of creditors or takes advantage of any insolvency statute or similar statute, or such filing is made by a Third Party, and such filing is not withdrawn within sixty (60) days of the filing date, or if a receiver or trustee is appointed for the property and assets of the Party and the receivership proceedings are not dismissed within sixty (60) days of such appointment.
- 12.6 Accrued Rights. Termination of the Agreement for whatever reason shall not affect the accrued rights of either Quintiles or Discovery arising under or out of this Agreement. Termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. In particular, upon termination for any reason, Discovery shall (i) pay Quintiles all fees for Services rendered which are due and owing to Quintiles because of any completed performance of Quintiles' obligations prior to

the effective date of termination, and (ii) pay all pass-through expenses actually incurred by Quintiles prior to the effective date of termination; and (iii) pay any other costs which have been expressly identified as being due upon termination.

- 12.7 Right to Receive Data. Upon termination, and upon full satisfaction of all outstanding invoices, Discovery shall have the right to receive from Quintiles all data attendant or related to Services or other sales and marketing activities under this Agreement.
- 12.8 Survival. The following provisions shall survive any expiration or termination of this Agreement, and if time periods are specified, for the period of time specified: Sections 1.1,1.4, 4.7, 4.8, 4.9, 5.5.3, 6.2.2, 7.1, 7.2, 7.4, 7.5 (last sentence only), 7.6 (first sentence only), 8.5, 9.2, 9.4, 9.5, 9.6, 12.6, 12.7 and Articles 10, 11, 13, 14 and 15.
- 12.9 Loss of Product Rights. Discovery holds the rights to the Product under an exclusive license from a Third Party. This Agreement shall automatically terminate if Discovery's license rights to the Product terminate in the Territory.

#### ARTICLE 13

#### SALES FORCE CONVERSION

- 13.1 Right to Convert Sales Force. Discovery shall have the right to offer Discovery employment to the Quintiles Personnel who are members of the Sales Force at the end of the Term, the end of any Extension Term, or earlier upon a termination of this Agreement by Discovery under Section 12.2 or 12.5. In the event Discovery desires to convert some or all of the Sales Force to its employment, it shall provide Quintiles notice of such election at least three (3) months prior to the end of the Term, or with its notice of termination under Section 12.3 or 12.5, as the case may be. Discovery shall pay Quintiles a fee of [\*\*\*] for each member of the Quintiles Personnel who is a member of the Sales Force actually hired by Discovery.
- 13.2 Transition Plan. In the event Discovery decides to convert the Sales Force, in accordance with Section 13.1, the Parties shall promptly meet and determine a transition plan, which shall include a schedule for actions which will enable a smooth transition date for all Quintiles Personnel: (i) who may be offered employment by Discovery; (ii) who may not be offered such employment; and (iii) who may decline such offers. Unless another timetable is established by the JCC, no later than [\*\*\*] before the end of the full scheduled Term or otherwise within [\*\*\*] from an applicable termination, Discovery shall identify for Quintiles the names of Quintiles Personnel who have elected to accept employment offers from Discovery and those who have not been offered employment or have declined an employment offer.

- 13.3 Discovery Determination. Discovery shall make an independent determination regarding the qualifications and suitability of Quintiles Personnel to be offered employment by Discovery, and the terms of such offers, if any. Solely to the extent permitted by applicable law or as otherwise may be lawfully allowed by appropriate prior written consent of the Quintiles Personnel (which Quintiles shall endeavor to obtain as promptly as reasonably practicable at Discovery's reasonable expense), relevant information contained in the personnel files of Quintiles Personnel shall be disclosed to Discovery, including, without limitation, resumes, applications, performance appraisals or disciplinary records, or the results of drug screens, motor vehicle or background reports. Notwithstanding the foregoing, Quintiles shall notify Discovery of any material violation by any Quintiles Personnel of the PDMA.
- 13.4 Proprietary Information. In the event of any Sales Force conversion under this Article 13, the Quintiles Personnel who become employed by Discovery may continue to use in their employment by Discovery any and all Product knowledge that they gained while in the employment of Quintiles, including, without limitation, knowledge regarding Product customers, competition, selling techniques, and the like.

#### DISPUTE RESOLUTION

- 14.1 Governing Law. This Agreement, including, without limitation, the interpretation, performance, enforcement, breach or termination thereof and any remedies relating thereto, shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, as applied to agreements executed and performed entirely in the State of Delaware, without regard to conflicts of law rules.
- 14.2 Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the JCC, which will use its good faith efforts to resolve the Dispute within ten (10) days. If the JCC is unable to resolve the Dispute in such period, the JCC will refer the Dispute to the Chief Executive Officers of Discovery and Quintiles Corp. For all Disputes referred to the Chief Executive Officers, the Chief Executive Officers shall use their good faith efforts to meet at least two times in person and to resolve the Dispute within ten (10) days after such referral.

## 14.3 Arbitration.

(a) If the parties are unable to resolve any Dispute under Section 14.2, then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 14.3 Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining

order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

- (b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by Discovery, one by Quintiles, and the third by the two so chosen. If both or either of Discovery or Quintiles fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this agreement, and any such party need not comply with the procedural provisions of this Section 14.3 in order to assert such counterclaim(s).
- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in Wilmington, Delaware or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60) day period. In addition, the following rules and procedures shall apply to the arbitration:
- (e) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 14.3.
- (f) The decision of the arbitrators, which shall be in writing and state the findings the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.
- (g) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.
- (h) The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 14.3, and the costs of the arbitrator(s) shall be equally divided between the parties; provided, however, that each party shall bear the costs incurred in connection

with any Dispute brought by such party that the arbitrators determine to have been brought in bad faith.

- (i) Except as provided in the last sentence of Section 14.3(a), the provisions of this Section 14.3 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising with regard to this Agreement. Any party commencing a lawsuit in violation of this Section 14.3 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.
- 14.4 Costs. The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute, and the costs of mediator(s) and arbitrator(s) shall be equally divided between the parties.

#### ARTICLE 15

### **MISCELLANEOUS**

- 15.1 Return of Materials. At the completion of the services by Quintiles or termination pursuant to Article 12, all materials and all other data owned by Discovery under this Agreement, regardless of the method of storage or retrieval, shall as promptly as practicable either be delivered to Discovery in such form as is then currently in the possession of Quintiles or disposed of, at the direction and written request of Discovery unless such materials are otherwise required to be stored or maintained by Quintiles as a matter of law or regulation. Discovery shall pay the reasonable costs associated with either of the above options.
- 15.2 Nonsolicitation of Employees. Except as otherwise provided herein, during the Term and for a period of [\*\*\*] thereafter, each Party agrees that neither it nor any of its Affiliates, divisions or operating groups that directly participates in or is directly responsible for the development or commercialization of the Product pursuant to this Agreement shall, directly or indirectly, recruit, solicit or induce any employee of the other Party to terminate his or her employment with such other Party, without the express written consent from the other party.
- 15.3 Entire Agreement; Amendment. This Agreement, and the other agreements referred to herein (or entered into as of the date hereof) between the Parties (or between Discovery and PharmaBio), set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.4 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides written notice to the other Party. Such excused performance shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe; provided, however, the payment of invoices due and owing hereunder at the time of the force majeure shall not be delayed by the payor because of a force majeure affecting the payor.

15.5 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid, express delivery service or personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Quintiles: Quintiles Transnational Corp.

4709 Creekstone Drive, Suite 200

Durham, NC 27703

Attention: Chief Executive Officer

Fax: (919) 998-7456 Phone: (919) 998-2000

General Counsel, Quintiles Transnational Corp. With a copy to:

4709 Creekstone Drive, Suite 200

Durham, NC 27703 Fax: (919) 998-2090 Phone: (919) 998-2080

Discovery Laboratories, Inc For Discovery:

350 South Main Street, Suite 307

Doylestown, PA 18901-4874

Fax: (215) 340-3940 Phone: (215) 340-4699

With a copy to: Roberts, Sheridan & Kotel

The New York Practice of

Dickstein Shapiro's Corporate & Finance Group

1177 Avenue of the Americas New York, NY 10036-2714 Attn: Ira L. Kotel

Phone: (212) 835-1400

Fax:

or to such other destination as either Party may hereafter notify the other Party in accordance with this section.

- 15.6 Consents Not Unreasonably Withheld or Delayed. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions are made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.
- 15.7 Maintenance of Records. Each Party shall keep and maintain all records required of it by law or regulation with respect to the Product and shall make copies of such records available to the other Party upon request.
- 15.8 United States Dollars. References in this Agreement to "Dollars" or "\$" shall mean the legal tender of the United States of America.
- 15.9 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.
- 15.10 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.10 shall be null and void and of no legal effect.
- 15.11 Performance by Affiliates. Obligations under this Agreement may be performed by Affiliates of Quintiles and Discovery only with the prior consent of the other Party. In the event any such performance is carried out by Affiliates with the prior consent of the other Party, each of Quintiles and Discovery guarantees performance of this Agreement by its Affiliates. No Affiliate of a Party may make decisions inconsistent with this Agreement, amend the terms of this Agreement or act contrary to its terms in any way.
- 15.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 15.13 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

- 15.14 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- 15.15 Ambiguities. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 15.16 Headings. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section
- 15.17 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

DISCOVERY LABORATORIES, INC.
By: /s/ David L. Lopez
Print: David L. Lopez
Title: Vice President and General Counsel
Date: December 10, 2001
QUINTILES TRANSNATIONAL CORP.
By: /s/ Thomas C. Perkins
Print: Thomas C. Perkins
Title: Vice President and Deputy General Counsel

Date: December 10, 2001

written.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the date and year first above

#### EXHIBIT A

#### **DEFINITIONS**

The following terms shall have the following meanings as used in this Agreement:

- 1. "Affiliate" means, as to any Party, any corporation or business entity controlled by, controlling, or under common control with such Party. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or income interest in such corporation or other business entity, or such other relationship as, in fact, constitutes actual control.
- 2. "FDA" means the U.S. Food and Drug Administration.
- 3. "Field Manager" means a member of the Sales Force having the responsibilities set forth on Schedule III for such job title.
- "Fully Loaded Cost" will have the meaning provided in Section 3.3.
- 5. "Quintiles Personnel" means any individual who is performing any part of the services hereunder on behalf of Quintiles.
- 6. "Joint Commercialization Committee" or "JCC" means the joint committee formed pursuant to Section 2.1.
- 7. "Marketing Plan" means a plan detailing the activities to be performed by each Party in the Territory as more fully described in Article 3 hereof.
- 8. "Marketing Services" means such pre- and post-launch promotional and marketing activities as are included in the Marketing Plan and any other activities identified by the JCC in furtherance of the objectives of this Agreement, which activities are allowed by the FDA or under the Food Drug & Cosmetic Act and its attendant regulations and as may be allowed by applicable regulatory authorities and the AMA Guidelines on Gifts to Physicians. Such activities may include without limitation, educational programs, symposia, poster-sessions, seminars for physicians, market research, pricing studies, development of promotional activities and advertising agency fees. Such activities may include marketing input into clinical strategic planning activities, i.e. protocol development, future indications, clinical and/or marketing studies.
- 9. "National Sales Manager" means the leader of the Sales Force having the responsibilities set forth on Schedule III for such job title.
- 10. "PDMA" means the Prescription Drug Marketing Act.
- 11. "Product" means the product currently known as Surfaxin, as such name may change from time to time, for any and all formulations and delivery mechanisms for the indications of (x)

- idiopathic respiratory distress syndrome ("IRDS") and (y) meconium aspiration syndrome ("MAS").
- 12. "Product Launch" or "Launch" means the first date upon which the Product is shipped by Discovery in the United States for commercial sale.
- 13. "Project Administrator" means the Quintiles employee at the headquarters office who will provide administrative support for the National Sales Manager.
- 14. "Promotional Materials" means written materials generated for the purpose of promotion and sale of the Product, in all cases with the prior written approval of Discovery.
- 15. "Sales Force" means those Quintiles Personnel who shall possess suitable expertise and who shall use diligent efforts to promote and sell the Product at a level which is consistent with those marketing efforts normally used for similar products in the pharmaceutical industry, including without limitation Sales Representatives, Field Managers, National Sales Manager and Project Administrator who promote the Product under this Agreement.
- 17. "Sales Force Commencement Date" shall mean the first date upon which Quintiles provides Sales Representatives under this Agreement.
- 18. "Sales Representative" means an employee of Quintiles: who is responsible for meeting with customers and physicians and others who can buy (or influence the buying process and decision regarding) the Product. The responsibilities of a Sales Representative are set forth on Schedule III.
- 19. "Sample" means units of Product distributed by Quintiles, and for complimentary distribution to patients by practitioners licensed to recommend Product, whether packaged as individual samples or as trade packages.
- 20. "Term" shall have the meaning provided in section 12.1.
- 21. "Territory" means the United States of America (including Puerto Rico).
- 22. "Third Party" means any entity or person other than Quintiles or Discovery or an Affiliate of either of them.
- 23. "Work Order" means a specific order in a form approved by the JCC for Marketing Services to be performed by Quintiles or an Affiliate.

#### EXHIBIT B

## MARKETING PLAN OUTLINE (Example only. JCC may use its own format)

## I. Executive Summary

## II. Market Analysis

- o Market
- o Products
- o Future Outlook

## III. Product Profile

- o Product Description
- o Indications
- o Clinical Experience and Program
- o Formulation, Packaging and Administration

## IV. SWOT Analysis

## V. 5 year Sales Forecasts

o Units, Dollars, Prescriptions, Market Share

## VI. Objectives

- o Awareness
- o Communication
- o Product Use
- o Sales
- o Market Share
- o Managed Care/Formulary

## VII. Key Issues

## VIII. Strategies

- o Product Positioning
- o Audiences
- o Sales Force
- o Pharmacoeconomics

## IX. Tactics

- o Pharmacoeconomics
- o Market Research
- o Medical Education
- o Publication Plan
- o Personal Selling Materials / Program
- o Clinical Support
- o Sales Force Support

- 0
- 0
- Sampling Managed Care / Formulary Territory Sales Force Effort 0
- Budget Following Year Χ.
- XI. Timelines

### SCHEDULE I

# QUINTILES RESPONSIBILITIES

- Quintiles will provide the following Quintiles Personnel to comprise the Sales Force:
- (a) Sales Representatives (as certain responsibilities and duties are defined in Schedule III, Section 1);
- (b) Field Managers (as certain responsibilities and duties are defined in Schedule III, Section 2);
- (c) National Sales Manager (as certain responsibilities and duties are defined in Schedule III, Section 3) and
  - (d) Project Administrator.
- Quintiles will be responsible for recruitment and re-recruitment of the Quintiles Personnel. Discovery will not be involved in the interviewing, selection or hiring of Quintiles Personnel.
- 3. Quintiles will only hire qualified Quintiles Personnel, defined as meeting a hiring profile to be established by the JCC.
- 4. Quintiles will manage all employer obligations in connection with the employment of Quintiles Personnel, including, but not limited to, discipline and termination of employees. Quintiles shall provide administrative resources for Field Managers, and communication between Quintiles and the Quintiles Personnel. Discovery will not be involved in the management or supervision of Quintiles Personnel
- 5. Training: The JCC will be responsible for developing a POA for training. In accordance with Section 6.1 of the Agreement, Quintiles shall be responsible for developing and providing training for the Sales Force regarding the Promotional Materials, disease and therapeutic areas, Product knowledge, Product marketing strategy and regional management in the Territory, Product recalls, reporting complaints and adverse events. The training will be conducted in a manner so as to meet or exceed the minimum training standards agreed to by the Parties and in accordance with all laws, rules, regulations and policies, including but not limited to the AMA Guidelines on Gifts to Physicians.
- 6. Quintiles shall be responsible for equipping the Sales Force with computer hardware and software needed to carry out the promotion of the Product. All Quintiles Personnel assigned to the Sales Force will receive a laptop computer and printer with interface cable. Quintiles shall be responsible for appropriate licenses and training, configuration, and replication/data line access. Quintiles shall provide upgrades to hardware or software as it deems necessary for successful promotion of the Product. In addition, Quintiles shall establish and provide help desk support for the hardware and software it provides.

- 7. Quintiles will provide the Sales Force the Quintiles Territory Management System ("ITMS") or other comparable sales force automation system and email/voice mail systems which will include components for call reporting, expense reporting, physician prescribing, call history, sales and market-share reporting, customized reports and communications. Quintiles shall also provide a sample tracking and compliance program. These systems and programs shall be of similar quality and effectiveness to that which Quintiles provides to its other clients. Quintiles may subcontract for all or a portion of the sample accountability services. Quintiles will make reasonable efforts to enable a reasonable number of Discovery personnel to have access to and be able to link into the ITMS and email/voicemail systems used by the Sales Force.
- 8. Quintiles shall be responsible for equipping the Field Managers with such other equipment as needed to carry out the promotion of the Product.
- 9. All promotional and detailing activities and obligations undertaken by Quintiles Personnel and the Sales Force hereunder shall be performed in accordance with the Marketing Plan. No Quintiles Personnel shall create Promotional Materials or other written materials relating to the Product without first submitting those materials to Discovery for and obtaining Discovery's written approval prior to use. Quintiles Personnel and the Sales Force shall make no statements, claims or undertakings to any person with whom they discuss or promote the Product that are inconsistent with the Promotional Materials. Promotional activities shall be in compliance with all applicable laws, rules, and regulations and policies. The Quintiles Personnel and the Sales Force shall not offer, pay, solicit or receive any remuneration to or from physicians or prescribers or health facilities, in order to induce referrals of or purchase of the Product. The Quintiles Personnel and the Sales Force shall have no direct contact with, nor shall the Quintiles Personnel and the Sales Force be involved with the delivery of the Product to patients of physicians, other than delivery of Samples directly to physicians or practitioners authorized to recommend the Product in the Territory. Quintiles shall permit Discovery to accompany Sales Representatives on sales calls from time to time with reasonable advance notice.
- 10. Quintiles shall provide monthly project management reports to Discovery in Quintiles' standard form within fifteen (15) business days after the end of each month.
- 11. Quintiles shall be responsible for organizing and coordinating the Product Launch meeting, POA meetings and national, regional or district meetings, subject to instructions from the JCC.
- 12. Quintiles Sales Representatives shall distribute the Samples provided by Discovery as directed in the Marketing Plan.
- 13. Quintiles shall administer an incentive bonus plan as determined by the JCC and designed to appropriately incent the Sales Representatives to use best efforts to promote the Product.

# SCHEDULE II

# DISCOVERY RESPONSIBILITIES & OBLIGATIONS

# DISCOVERY SALES PROJECT

- Discovery shall ensure that the Discovery sales, marketing and medical personnel are fully briefed as to the complementary role of the Quintiles 1. Personnel and ensure cooperation with the Quintiles Personnel.
- Discovery shall be responsible for: 2.

  - Communications within Discovery and from Discovery to Quintiles. Handling all aspects of order processing and fulfillment, invoicing 0 and collection, (may be accomplished through further Agreement with Quintiles or an Affiliate), Product supply, inventory and receivables.
  - Discovery Business Cards. 0

### SCHEDULE III

### **ROLE DEFINITIONS**

# 1. Sales Representative

### RESPONSIBILITIES AND DUTIES:

- o Generates sales within an assigned territorial boundaries.
- o Maintains current and prospective customer profiles and information.
- o Keeps current with Product, competitor products, and market knowledge.
- o Maintains a professional image for Discovery and the Product at all times.
- o Organizes territory-planning to meet sales and call goals.
- o Provides sales presentations: individual one-on-one, groups, in-services.
- o Maintains Sample inventories, distributes Samples, complies with Sample accountability procedures and policies.
- o Participates in all training programs.
- o Completes and submits in a timely manner all accountability and expense reports.
- o Monitors that Product is appropriately stocked by local distribution centers, hospitals and pharmacies.
- o Monitors that Product is on hospital formularies.
- o Attends trade shows as directed by National Sales Manager.

### SKILLS:

- o Initiative
- o Persuasiveness/Sales ability
- o Planning and Organizing
- o Individual Leadership/Influencing
- o Teamwork/Collaboration
- o Motivational Fit

# 2. Field Manager

- o Attains sales objectives within assigned districts.
- o Deploys resources to maximize district sales potential.
- o Implements Discovery Product strategies within district.
- o Maintains District budgets and accurate records on all sales activities.
- o Makes regular field visits to develop, train, supervise, motivate and monitor Sales Representative performance; completes field contact reports.
- o Makes final hiring decision; training and evaluation of Sales Representatives.
- o Documents and recommends all disciplinary actions to include warnings, suspensions, probation, terminations.
- o Communicates with Discovery management on a regular basis.
- o Submits a formal monthly report to Quintiles National Sales Manager.
- o Assists in the planning and delivery of initial training course.

- o Assists in the planning and delivery of POA or trimester meetings.
- o Monitors that Product is on managed care formularies that are within the Field Manager's district.

# 3. National Sales Manager

- o Hires, trains develops and evaluates Field Managers.
- o Develops, supervises, motivates and monitors performance of Field Managers.
- o Maintains project budgets.
- o Monitors days worked and directs Field Managers accordingly.
- o Prepares and submits monthly summary report to Quintiles and Discovery management
- o Serves as key point of contact for Discovery.
- o Approves all Sales Force disciplinary actions.
- O Develops initial training program for Sales Representatives and Field Managers.
- O Coordinates POA or trimester meetings; plans and conducts meetings with Discovery and its region management.
- o Coordinates submissions for national managed care formularies.
- o Directs coordination of Field Manager and Sales Representatives to attend trade shows as appropriate.

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by [\*\*\*], have been separately filed with the Securities and Exchange Commission.

## INVESTMENT AND COMMISSION AGREEMENT

This Investment and Commission Agreement (the "Agreement") is made as of December 10, 2001, by and between Discovery Laboratories, Inc., a Delaware corporation ("Discovery"), and PharmaBio Development, Inc., a North Carolina corporation ("PharmaBio").

### Background and Overview

- A. Discovery and Quintiles Transnational Corp. ("Quintiles"), an Affiliate of PharmaBio, have executed a Commercialization Agreement (herein so called) on the date hereof, pursuant to which Quintiles will provide exclusive Commercialization Services in the Territory for the Product.
- B. Discovery and PharmaBio have agreed that PharmaBio will fund the payments for the Commercialization Services, pursuant to the terms and conditions set forth herein.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

- 1.0 Definitions.
- "Affiliate" shall mean, as to any person or entity, any corporation or business entity controlled by, controlling, or under common control with such party or entity. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or income interest in such corporation or other business entity.
- 1.2 "Annual Period" shall mean a twelve-month period beginning on the Launch Date and each anniversary thereof.
- 1.3 "Commercialization Expenses" shall mean the fees and expenses payable to Quintiles for the Commercialization Services.
- "Commercialization Services" shall mean (i) sales and marketing services provided by Quintiles under the Commercialization Agreement after the Launch Date (including, but not limited to, services provided after the Launch Date related to the deployment and management of a dedicated sales force for the promotion of the Product), and (ii) services provided under the Commercialization Agreement before the Launch Date for the following specific activities: (x) recruitment, hiring and training for the sales force; (y) establishing sales force targets, territory alignments, mapping and sales

force optimization, and validation of practitioner's state license; and (z) conducting launch meetings and the national, regional and district meetings.

- 1.5 "Commission Term" means the ten (10) consecutive Annual Periods beginning on the Launch Date.
- 1.6 "FDA" shall mean the US Food and Drug Administration.
- "JCC" shall mean the joint commercialization committee established under the Commercialization Agreement. If for any reason the Commercialization Agreement is terminated or the JCC is otherwise disbanded under the Commercialization Agreement, then Discovery and PharmaBio shall in good faith, as promptly as practicable, form an advisory body composed of an equal number of designees of Discovery and PharmaBio (the "Advisory Board"); provided, that Discovery shall have at least the same rights and authority with respect to such advisory body as it had with respect to the JCC (and PharmaBio shall have at least the same rights and authority with respect to such advisory body as Quintiles had with respect to the JCC). In such event, (i) the Advisory Board shall perform all of the obligations under this Agreement that would otherwise have been performed by the JCC, and all references to the JCC herein shall thereafter be deemed references to the Advisory Board, and (ii) PharmaBio shall appoint members to the Advisory Board who are at least as experienced in pharmaceutical marketing and sales activities as Quintiles' members of the JCC.
- 1.8 "Launch Date" shall mean the date upon which the Product is first shipped

- in the United States for commercial sale.
- 1.9 "Maximum Investment" shall mean \$[\*\*\*] per year for each of the seven (7) years following the Launch Date. (All dollar references in this Agreement shall refer to United States Dollars).
- 1.10 "Minimum Sales Force Level" shall mean the sales force size for the Product recommended by the JCC from time to time as provided for in the Commercialization Agreement (provided that, for purposes of such calculation, the recommended sales force size will not exceed the sales force size that could be reasonably supported by the amount of Commercialization Expenses funded by PharmaBio under this Agreement). If the parties are not able to unanimously agree to such sales force size calculation, then such calculation shall be made in accordance with the dispute resolution process set forth in Section 11 of this Agreement.

- 1.11 "Net Sales" means the amount billed by Discovery or an Affiliate or any sublicensee, or on behalf of or for the benefit of Discovery or an Affiliate or any sublicensee, for sales of the Product to a third party in the Territory less: (i) discounts, including cash and quantity discounts, charge-back payments, refunds and rebates granted to managed health care or similar organizations or to federal, state and local governments (including, without limitation, Medicaid rebates), their agencies, and purchasers and reimbursers or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups, (ii) credits or allowances actually granted upon claims, damaged goods, rejections or returns of such Product, including recalls, regardless of the party requesting such, (iii) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Product, to the extent billed, (iv) taxes, duties or other governmental charges levied on, absorbed or otherwise imposed on sale of such Product, including without limitation value-added taxes, or other governmental charges otherwise measured by the billing, when included in billing, as adjusted for rebates, charge-backs and refunds, and (v) bad debts related to Product sales (defined as any bills unpaid for 120 days after due), provided that (a) any subsequent collection by Discovery on such bad debt shall be restored as Net Sales at the time of collection, and in the amount, of such collection, and (b) Discovery shall follow commercially reasonable practices of collecting and otherwise administering debt related to Product sales. Provided, however, in no event shall Net Sales be less than [\*\*\*] of the gross sales of the Product in the Territory.
- 1.12 "Product" shall mean the product currently known as Surfaxin, as such name may change from time to time, for any and all formulations and delivery mechanisms (i) for the indications of (x) idiopathic respiratory distress syndrome ("IRDS") and (y) meconium aspiration syndrome ("MAS"); and (ii) solely for the purposes of Section 1.11, include all "off-label" uses.
- 1.13 "Territory" shall mean the United States (including Puerto Rico).
- 2.0 Commercialization Agreement.

The Commercialization Agreement is in the form attached hereto as Exhibit A. All defined terms used herein but not defined in this Agreement shall have the meanings set forth in the Commercialization Agreement.

- 3.0 Investment and Commission; Related Agreements.
- 3.1 PharmaBio will support the commercialization of the Product as follows:
  - (a) PharmaBio shall fund one hundred percent (100%) of the Commercialization Expenses for the period ending on the seventh anniversary of the Launch Date (the "Commitment Period"), subject to the Maximum Investment for each such year and the other terms and conditions in this Agreement.
  - (b) PharmaBio shall fund the amounts payable under Section 3.1(a) by paying the invoices submitted by Quintiles that correspond to the applicable Commercialization Expenses that accrue during the Commitment Period, which payments shall be made by PharmaBio within twenty (20) days of PharmaBio's receipt of the invoice. As directed by Discovery, PharmaBio shall make such payment through either (i) a payment to Discovery, or (ii) an inter-company payment directly to Quintiles.
- 3.2 In consideration for the performance of PharmaBio of its funding commitments set forth in Section 3.1, Discovery shall pay PharmaBio a commission on Net Sales during the Commission Term. The commission payments payable by Discovery to PharmaBio with respect to each Annual Period are as follows:

Annual Period during the Commission Term	Commission on Net Sales
1	[***]
2	[***]
3	[***]
4	[***]
5	[***]
6	[***]
7	[***]
8	[***]
9	[***]
10	[***]

The commission payments under this Section 3.2 shall be paid as soon as reasonably practicable following the end of each calendar quarter (but not later than thirty (30) days following the end of each calendar quarter) during the ten (10) Annual Periods in the Commission Term.

- 3.3 The JCC shall take the following actions a reasonable time prior to the Launch Date: (i) prepare a marketing plan for the Product, including a sales forecast; (ii) agree to the Commercialization Services reasonably necessary to support sales of the Product in the Territory at the levels set forth in such sales forecast (including the optimum sales force size to support such sales of the Product); and (iii) agree to a related budget for Commercialization Expenses. On or about each anniversary of the Launch Date, the JCC shall update such items. The above actions will be taken by the JCC with due regard to the size and value of the market for the Product in the Territory, taking into account, among other variables, the clinical safety and efficacy of the Product (and related labeling claims), the competitive environment in which the Product is being promoted, and a reasonable budget for the sales and marketing activities. Notwithstanding anything to the contrary in this Agreement or the procedures for JCC decisions set forth in the Commercialization Agreement, the parties agree to the following:
  - (a) Discovery shall have the final decision on the marketing plan for the Product and the activities (including the Commercialization Services) necessary to implement such marketing plan.
  - (b) Notwithstanding anything to the contrary in this Agreement, PharmaBio shall have the final decision on the amount of Commercialization Expenses that will be funded by PharmaBio under Section 3.1 of this Agreement, provided that PharmaBio shall not act unreasonably or in bad faith in determining such amount. For purposes of the preceding sentence, PharmaBio shall be deemed to have acted unreasonably or in bad faith if PharmaBio sets the amount of Commercialization Expenses that PharmaBio is willing to fund under Section 3.1 at a level that cannot reasonably be justified in light of the size and value of the market for the Product. Notwithstanding anything to the contrary in this Agreement, PharmaBio cannot be deemed to have acted unreasonably or in bad faith for purposes of this Section 3.3(b) by failing to fund Commercialization Expenses in excess of the Maximum Investment. Further, PharmaBio shall not be deemed to have acted unreasonably or in bad faith for purposes of this Section 3.3(b) by failing to fund Commercialization Expenses (or suspending such funding) upon certain events impacting the marketing of the Product that are not within PharmaBio's control, which is defined as: (i) a material breach by Discovery of any obligation or representation or warranty under this Agreement; (ii) withdrawal of Product caused by actual or threatened regulatory action by the FDA or other governmental entity, safety concerns relating to Product, the loss of Discovery's license rights or other rights to Product, or similar cause; (iii) significant unforeseen new information regarding the safety or efficacy of Product which has a material adverse effect on the sales of Product; or (iv) other material factors adversely impacting Net Sales of the Product that were not reasonably foreseeable by, or within the control of, PharmaBio as of the date hereof. If PharmaBio shall decide not to fund some amount of the Commercialization Expenses, then (i) Discovery shall be entitled to fund such amounts

directly, and (ii) subject to prior termination as provided for in Section 7.0, PharmaBio's right to receive the commission payments set forth in Section 3.2 shall not be reduced.

- 3.4 Discovery shall use commercially reasonable efforts to commercialize the Product in the Territory. In this regard, Discovery will provide a sales force of a size not less the Minimum Sales Force Level during the Commitment Period. If, at any time during such period, Discovery reduces the Product sales force below the Minimum Sales Force Level for a period of more than [\*\*\*], then Discovery and PharmaBio will negotiate in good faith to restructure PharmaBio's commitments under Section 3.1 and the corresponding commission amounts under Section 3.2 , which negotiations will take into account the implications of the reduced sales force size on future sales of the Product. If the parties are unable to agree to such restructuring within thirty (30) days after PharmaBio gives written notice to Discovery of its intent to pursue a remedy under this Section 3.4 for Discovery's failure to maintain the Minimum Sales Force Level, then PharmaBio may, at its sole discretion by written notice to Discovery, elect to suspend the following: (i) all future funding obligations under Section 3.1; and (ii) the running of the Commission Term (including, without limitation, the then-current Annual Period). During the suspension period, PharmaBio shall continue to receive royalties at the rate equal to the commission amount applicable immediately prior to the effective date of the suspension period. If PharmaBio elects this remedy, the then operating Annual Period for commission payments under Section 3.2, and the funding commitments under Section 3.1, shall be suspended until the Minimum Sales Force Level is satisfied. Such Annual Period, and the funding commitments under Section 3.1, shall restart when the Minimum Sales Force Level is satisfied, at the same time point such Annual Period was suspended, such that PharmaBio enjoys the full length of the ten (10) Annual Periods described in Section 3.2 with the benefit of the Minimum Sales Force Level for seven (7) full twelve-month periods, and the term "Commission Term" shall, for all purposes under this Agreement, be extended accordingly. PharmaBio's remedies under this Section 3.4 shall not apply for any period that Quintiles fails to satisfy its sales force staffing obligations under the Commercialization Agreement. Notwithstanding anything herein to the contrary, PharmaBio's rights under this Section 3.4 shall be expressly subject to the provisions of Section 3.5.
- 3.5 In the event that Discovery terminates the Commercialization Agreement under Section 12.3 thereof, then:
  - (a) Discovery shall use commercially reasonable efforts in good faith to identify, retain and train a new sales force (the "New Sales Force") as soon as practicable to perform substantially similar functions as were to have been provided by Quintiles under the Commercialization Agreement;

- (b) During the period (the "Transition Period") beginning on the effective date of Discovery's termination of the Commercialization Agreement and ending on the first day of the month next following the date on which the New Sales Force begins detailing physicians:
  - (i) Discovery's obligation to provide the Minimum Sales Force Level shall be suspended;
  - (ii) PharmaBio shall have none of the suspension or other remedial rights that it would otherwise have under Section 3.4 as a result of Discovery's failure to provide the Minimum Sales Force Level or otherwise;
  - (iii) in lieu of the commission rate set forth in Section 3.2, Discovery's commission obligation to PharmaBio hereunder shall equal the product of (A) the commission rate set forth in Section 3.2 multiplied by (B) the percentage that Net Sales is during the Transition Period of projected Net Sales for the Transition Period (based on the JCC's most recent Net Sales forecast, prorated, to the extent necessary, on a reasonable, good faith basis); and
  - (iv) the Commission Term shall continue to run during the Transition Period such that it will continue to expire on the tenth (10th) anniversary of the Funding Date.
- (c) PharmaBio's funding commitments under Section 3.1 shall continue in full force and effect, and all references hereunder to Quintiles shall be deemed to refer to the New Sales Force (and all references to (i) the Commercialization Agreement hereunder shall be deemed to refer to the agreement, if any, pursuant to which Discovery retains the New Sales Force and (ii) Quintiles hereunder shall be deemed to refer to the New Sales Force or the contract provider of the New Sales Force, as applicable).
- 3.6 As of the date hereof, the parties have entered into a Common Stock and Warrant Purchase Agreement. The representations and warranties set forth in Article IV of the Stock Purchase Agreement with respect to Discovery (excluding Sections 4.02, 4.14 through 4.18 and 4.20, and after modifying Section 4.04 so that "Transaction Documents" shall mean this Agreement) and in Article V with respect to PharmaBio (excluding Section 5.03 through 5.06 and after modifying Section 5.02 so that "Transaction Documents" shall mean this Agreement) are incorporated in this Agreement by reference and form part of the consideration given to each party in exchange for the other party's commitments set forth herein. Discovery agrees to continue to exercise diligent efforts to submit the NDA (as defined in the Commercialization Agreement) for the Product to the FDA and to reasonably diligently seek FDA approval for the Product. Upon the approval of either the MAS or the IRDS indication, Discovery shall continue to use commercially reasonable

efforts to submit the NDA for the other indication to the FDA and to seek  $\mbox{FDA}$  approval of such.

- 3.7 Each Party shall keep or cause to be kept such records as are required to determine, in a manner consistent with generally accepted accounting principles in the United States, the sums or credits due under this Agreement. Upon the written request of either party, the other party shall permit an independent certified public accountant appointed by such party and reasonably acceptable to the other party, accompanied by representatives of the financial department of such party at reasonable times and upon reasonable notice, to audit only those records as may be necessary to determine the correctness or completeness of any report or payment made under this Agreement. Results of any such audit shall be (i) limited to information relating to the Product, (ii) made available to both parties and (iii) subject to the confidentiality protections set forth herein. The party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit discloses a variance of more than five percent (5%) from the amount of the original report, royalty or payment calculation. In such case, the party being audited shall bear the full cost of the performance of such audit.
- 3.8 Without the prior approval of PharmaBio, Discovery shall not, nor shall it allow any Affiliate or third party acting on behalf of or for the benefit of Discovery or any Affiliate to, commercialize a product that would reasonably be expected to compete with the Product in the Territory during the Commission Term.
- 3.9 The parties acknowledge and agree that (i) Discovery may pursue additional formulations and/or delivery technologies for the Product, which may result in pre-launch and launch promotional activities for the additional formulations and/or delivery technologies, (ii) such pre-launch and launch promotional activities are within the scope of the Commercialization Agreement, and (iii) the expenses associated with such pre-launch and launch promotional activities will be considered "Commercialization Expenses" for purposes of this Agreement and shall be subject to PharmaBio's funding obligations hereunder in accordance with the terms and limitations set forth herein.
- PharmaBio shall make milestone payments to Discovery pursuant to the terms 3.10 set forth in this Section 3.10. The "First Milestone" (herein so called) shall be paid on the earlier to occur of the receipt of FDA approval ("FDA Approval") to commercialize (x) the MAS Indication or (y) the IRDS Indication. The amount of the First Milestone shall be seventy percent (70%) of the outstanding principal (as of the controlling FDA Approval) under the Loan Agreement (herein so called), dated as of the date hereof, between PharmaBio and Discovery. The "Second Milestone" (herein so called) shall be paid on the earlier to occur of (x) the completion by Quintiles or an appropriate Affiliate of a written assessment and report in customary form indicating the "approvability" by the FDA of Discovery's NDA for the Product for the indication that was not approved as a condition for the First Milestone, which shall include without limitation an assessment and report as to the quality of the documentation comprising such NDA and the clinical data included in such NDA, or

- (y) the issuance by the FDA of a letter in customary form indicating that Discovery's NDA for the Product for such indication is "approvable." The amount of the Second Milestone payment shall be the remaining principal amounts outstanding under the Loan Agreement. PharmaBio shall have the right to apply the First Milestone and Second Milestone payments against any amounts then outstanding under the Loan Agreement.
- 4.0 Confidentiality and Ownership of Information.
- 4.1 Discovery on the one part and PharmaBio on the other part each acknowledges that, in the course of performing its obligations hereunder, it may receive information from the other party which is proprietary to the disclosing party and which the disclosing party wishes to protect from public disclosure ("Confidential Information"). Each receiving party agrees to retain in confidence, during the Commission Term, and thereafter for a period of seven (7) years, all Confidential Information disclosed to it by or on behalf of the other party, and that it will not, without the written consent of such other party, use Confidential Information for any purpose other than the purposes indicated herein. These restrictions shall not apply to Confidential Information which: (i) is or becomes public knowledge (through no fault of the receiving party); (ii) is made lawfully available to the receiving party by an independent third party that, to the knowledge of the receiving party, is under no duty of confidentiality to the disclosing party; (iii) is already in the receiving party's possession at the time of receipt from the disclosing party (and such prior possession can be demonstrated by competent evidence by the receiving party); (iv) is independently developed by the receiving party and/or Affiliates (and such independent development can be demonstrated by competent evidence by the receiving party); or (v) is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by the receiving party, provided, however, if reasonably possible, such receiving party gives the disclosing party sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such Confidential Information and, thereafter, the receiving party discloses only the minimum Confidential Information required to be disclosed in order to comply.
- 4.2 PharmaBio on the one hand and Discovery on the other hand shall limit disclosure of the other party's Confidential Information to only those of their respective officers, representatives, agents and employees (collectively "Agents") who are directly concerned with the performance of this Agreement and have a legitimate need to know such Confidential Information in the performance of their duties.
- 4.3 All Discovery inventions, processes, know-how, patents, trade secrets, copyrights, trade names, trademarks, service marks, marketing materials, proprietary materials or other intellectual property of any kind, and all improvements to any of the foregoing (collectively, "Discovery Property"), disclosed, used, improved, modified or developed in connection with the relationship contemplated by this Agreement shall remain the sole and exclusive property of Discovery. PharmaBio shall not have any right, title or interest in or to any Discovery Property.

- 4.4 Discovery acknowledges that PharmaBio (and its Affiliates) possess certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, computer technical expertise and software, and business practices, including, but not limited to the Innovex Territory Management System (ITMS), which have been independently developed by PharmaBio and/or its Affiliates (collectively "Quintiles Property"). Any Quintiles Property or improvements thereto which are disclosed, used, improved, modified or developed by Quintiles under or during the term of this Agreement shall remain the sole and exclusive property of PharmaBio or the respective Affiliates.
- 5.0 Independent Contractor Relationship.

For the purposes of this Agreement, Discovery and PharmaBio are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer and employee or joint venturers. Neither Discovery nor PharmaBio shall have the power or right to bind or obligate the other party, nor shall either party hold itself out as having such authority.

6.0 Termination.

Either party may terminate this Agreement for material breach upon thirty (30) days written notice specifying the nature of the breach, if such breach (i) has not been substantially cured within the thirty (30) day period or (ii) is not curable within such 30-day period and the breaching party has not commenced and diligently continued during such 30-day period reasonable actions to cure such breach. During the 30-day cure period for termination due to breach, each party will continue to perform its obligations under this Agreement. Either party may terminate this Agreement immediately upon provision of written notice if the other party becomes insolvent or files for bankruptcy or is not otherwise able to pay its obligations as they become due and payable.

- 7.0 Indemnification and Liability Limits.
- 7.1 PharmaBio shall indemnify, defend and hold harmless Discovery, its Affiliates and its and their respective directors, officers, employees and agents from and against any and all losses, claims, actions, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and court costs) (collectively, "Losses"), resulting from any: (i) material breach by PharmaBio (or its employees) of its obligations hereunder; (ii) willful misconduct or grossly negligent acts or omissions of PharmaBio or its employees; and (iii) material violation by PharmaBio or its employees of any municipal, county, state or federal laws, rules or regulations applicable to the performance of PharmaBio's obligations under this Agreement; except, in each case, to the extent such Losses are determined to have resulted from the gross negligence or willful misconduct of Discovery or its employees.
- 7.2 Discovery shall indemnify, defend and hold harmless PharmaBio and its Affiliates and their respective directors, officers, employees and agents from and against any and all

Losses resulting from: (i) any third party claim arising from the manufacture, storage, packaging, production, transportation, distribution, use, sale or other disposition of the Product; (ii) material breach by Discovery (or its employees) of its obligations hereunder; (iii) willful misconduct or grossly negligent acts or omissions of Discovery or its employees; and (iv) material violation by Discovery or its employees of any municipal, county, state or federal laws, rules or regulations applicable to the performance of Discovery's obligations under this Agreement, except, in each case, to the extent such Losses are determined to have resulted from the gross negligence or willful misconduct of PharmaBio or any of its employees.

- 7.3 In the event of a third party claim or lawsuit, the party seeking indemnification hereunder (the "Indemnified Party") shall give the party obligated to indemnify (the "Indemnifying Party") prompt written notice of any claim or lawsuit (including a copy thereof), provided that the failure of an Indemnified Party to notify the Indemnifying Party on a timely basis will not relieve the Indemnifying Party of any liability that it may have to the Indemnified Party unless the Indemnifying Party demonstrates that the defense of such action is materially prejudiced by the Indemnified Party's failure to give such notice. The Indemnified Party and its employees shall fully cooperate with Indemnifying Party and its legal representatives in the investigation and defense of any matter the subject of indemnification, which defense shall be managed by the Indemnifying Party in a manner, including the selection of legal counsel, reasonably acceptable to the Indemnified Party. The Indemnified Party shall not unreasonably withhold its approval of the settlement of any such claim, liability, or action by Indemnifying Party covered by this indemnification provision; provided that such settlement does not include an admission or acknowledgement of liability or fault of the Indemnified Party.
- 7.4 Neither PharmaBio nor Discovery, nor any of such party's Affiliates, directors, officers, employees, subcontractors or agents shall have, under any legal theory (including, but not limited to, contract, negligence and tort liability), any liability to any other party hereto for any loss of opportunity or goodwill, or any type of special, incidental, indirect or consequential damage or loss, in connection with or arising out of this Agreement. For the avoidance of doubt, a claim by PharmaBio for commissions on Net Sales payable by Discovery hereunder or a claim by Discovery for payments pursuant to Section 3.1 shall not be limited in any way pursuant to the provisions set forth in the preceding sentence.

# 8.0 Notices.

Any notice required to be given by either party shall be in writing. All notices shall be to the parties and addresses listed below, and shall be deemed sufficiently given (i) when received, if delivered personally or sent by facsimile transmission with confirmed receipt, or (ii) one business day after the date mailed or sent by an internationally recognized overnight delivery service with charges prepaid.

If to PharmaBio: PharmaBio Development, Inc.

4709 Creekstone Drive Durham, NC 27703 Attention: President Fax: 919-998-2090

With a copy to: General Counsel

PharmaBio Development, Inc.

4709 Creekstone Drive Durham, NC 27703 Fax: 919-998-2090

If to Discovery: Discovery Laboratories, Inc.

350 South Main Street, Suite 307

Doylestown, PA 18901

Attention: Robert J. Capetola, Ph.D., President and CEO

Fax: 215-340-3940

With a copy to: Roberts, Sheridan & Kotel

The New York Practice of

Dickstein Shapiro's Corporate & Finance Group

1177 Avenue of the Americas New York, NY 10036-2714 Attn: Ira L. Kotel

Facsimile: (212) 835-1400

### 9.0 Assignment.

No party may assign any of its rights or obligations under this Agreement to any third party without the written consent of the other party, except that Discovery may assign its rights or obligations under this Agreement to a bona fide third party that (i) acquires all of Discovery's business (a "Permitted Sale") provided that such party assumes all of Discovery's rights and obligations under this Agreement. Other than pursuant to a Permitted Sale, Discovery may not, without the written approval of PharmaBio, assign any of its rights in the Product in the Territory to a third party. PharmaBio may at any time assign or transfer any of its rights or obligations under this Agreement to an Affiliate so long as such Affiliate agrees in an enforceable written instrument to be bound by all the terms and conditions of this Agreement as if it were PharmaBio and a party thereto, which instrument shall be delivered a reasonably practicable time prior to such assignment. Nothing in this Section 9.0 shall preclude the transfer of a party's rights and obligations under this Agreement in conjunction with a merger in which such party is not the surviving entity.

## 10.0 General Provisions.

10.1 This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of Delaware, without giving effect to the principles of conflict of laws.

- 10.2 The provisions of Articles 1 (except for Section 1.7), 2, 45, 7, 8, 10 and 11 shall survive the termination of this Agreement for any reason.
- 10.3 This Agreement contains the entire understandings of the parties with respect to the subject matter herein and cancels all previous agreements (oral and written), negotiations and discussions dealing with the same subject matter. The parties, from time to time during the term of this Agreement, may modify any of the provisions hereof only by an instrument in writing duly executed by the parties.
- 10.4 No failure or delay on the part of a party in either exercising or enforcing any right under this Agreement will operate as a waiver of, or impair, any such right. No single or partial exercise or enforcement of any such right will preclude any other or further exercise or enforcement thereof or the exercise or enforcement of any other right. No waiver of any such right will have effect unless given in a signed writing. No waiver of any such right will be deemed a waiver of any other right.
- 10.5 If any part or parts of this Agreement are held to be illegal, void or ineffective, the remaining portions of this Agreement shall remain in full force and effect. If any of the terms or provisions are in conflict with any applicable statute or rule of law, then such term(s) or provision(s) shall be deemed inoperative to the extent that they may conflict therewith, and shall be deemed to be modified or conformed with such statute or rule of law. In the event of any ambiguity respecting any term or terms hereof, the parties agree to construe and interpret such ambiguity in good faith in such a way as is appropriate to ensure its enforceability and viability.
- 10.6 The headings contained in this Agreement are used only as a matter of convenience, and in no way define, limit, construe or describe the scope or intent of any section of this Agreement.
- 10.7 The individuals signing below are authorized and empowered to bind the parties to the terms of this Agreement.
- 10.8 Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions are made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised. For the avoidance of doubt, PharmaBio's funding decisions under Section 3.3(b) shall not be deemed a "consent or approval" for purposes of this Section 10.8.
- 11.0 Dispute Resolution:
- 11.1 Governing Law. This Agreement, including, without limitation, the interpretation, performance, enforcement, breach or termination thereof and any remedies relating thereto, shall be governed by and construed in accordance with the laws of the State

of Delaware, United States of America, as applied to agreements executed and performed entirely in the State of Delaware, without regard to conflicts of law rules.

11.2 Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the JCC, which will use its good faith efforts to resolve the Dispute within ten (10) days. If the JCC is unable to resolve the Dispute in such period, the JCC will refer the Dispute to the Chief Executive Officers of Discovery and Quintiles Corp. For all Disputes referred to the Chief Executive Officers, the Chief Executive Officers shall use their good faith efforts to meet at least two times in person and to resolve the Dispute within ten (10) days after such referral.

### 11.3 Arbitration.

- (a) If the parties are unable to resolve any Dispute under Section 11.2, then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 11.3 Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.
- (b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by Discovery, one by Quintiles, and the third by the two so chosen. If both or either of Discovery or Quintiles fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this agreement, and any such party need not comply with the procedural provisions of this Section 11.3 in order to assert such counterclaim(s).

- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in Wilmington, Delaware or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60) day period. In addition, the following rules and procedures shall apply to the arbitration:
- (e) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 11.3.
- (f) The decision of the arbitrators, which shall be in writing and state the findings the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.
- (g) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.
- (h) The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 11.3, and the costs of the arbitrator(s) shall be equally divided between the parties; provided, however, that each party shall bear the costs incurred in connection with any Dispute brought by such party that the arbitrators determine to have been brought in bad faith.
- (i) Except as provided in the last sentence of Section 11.3(a), the provisions of this Section 11.3 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising with regard to this Agreement. Any party commencing a lawsuit in violation of this Section 11.3 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

11.4 Costs. The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute, and the costs of mediator(s) and arbitrator(s) shall be equally divided between the parties.

IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

PHARMABIO DEVELOPMENT, INC. DISCOVERY LABORATORIES, INC.

By:

/s/ Thomas C. Perkins By /s/ David L. Lopez

------

17

Name: Thomas C. Perkins Name: David L. Lopez

Title: Vice President and General Title: Vice President and

Counsel General Counsel

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by [\*\*\*], have been separately filed with the Securities and Exchange Commission.

## COMMON STOCK AND WARRANT PURCHASE AGREEMENT

THIS COMMON STOCK AND WARRANT PURCHASE AGREEMENT (this "Agreement") is dated and entered into as of December 10, 2001, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Purchaser").

WHEREAS, the Company and Purchaser have entered into an Investment and Commission Agreement and a Loan Agreement, both dated as of the date hereof, and the Company and Quintiles Transnational Corp., an Affiliate of the Purchaser, have entered into a Commercialization Agreement also dated as of the date hereof (together with this Agreement, and the Warrants, collectively, the "Transaction Agreements"); and

WHEREAS, in connection with the foregoing, Purchaser desires to acquire and the Company is willing to issue and sell to Purchaser: shares of common stock, \$.001 par value per share, of the Company (the "Common Stock"); and warrants to purchase shares of Common Stock as described herein, subject to the terms and conditions specified herein;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties agree as follows:

# ARTICLE I DEFINITIONS

1.01 Definitions. For purposes of this Agreement, in addition to the terms defined elsewhere herein, the following terms shall have the meanings set forth below:

"Affiliate" shall mean, as to any person or entity, any corporation or business entity controlled by, controlling, or under common control with such party or entity. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or income interest in such corporation or other business entity.

"beneficial ownership" or "beneficially own" shall have the meaning given under Rule 13d-3 promulgated under the Exchange Act.

"Business Day" shall mean any day other than a Saturday, Sunday or legal holiday on which banks in North Carolina and New York are open for the conduct of their banking business.

"Closing" shall have the meaning specified in Section 2.02(a) herein.

"Closing Date" shall have the meaning specified in Section 2.02(a) herein

"Event of Default" shall have the meaning given such term in the Loan Agreement.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

"FFDCA" shall mean the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and all regulations promulgated thereunder.

"Five-Day Average Trading Price" of the Common Stock on any date shall mean the average of the closing sales prices quoted on the Nasdaq SmallCap Market for the five (5) trading days prior to such date.

"knowledge" shall mean, when used with respect to the Company, the knowledge of the executive officers and directors of the Company.

"Loan Agreement" shall mean the Loan Agreement dated as of the date hereof between the Company and Purchaser, as amended, modified or supplemented from time to time.

"Registrable Securities" shall mean (i) the Shares, (ii) the Warrant Shares, and (iii) any Common Stock issued as a dividend or other distribution with respect to, or in exchange for or in replacement of, such above-described securities; provided however, that "Registrable Securities" shall not include any securities sold by a person either pursuant to a registration statement or

Rule 144.

"Rule 144" shall mean Rule 144 as promulgated by the SEC under the Securities Act, as such Rule may be amended from time to time, or any similar successor rule that may be promulgated by the SEC.

"Securities Act" shall mean the Securities Act of 1933, as amended.

"SEC" shall mean the Securities and Exchange Commission.

"Shares" shall mean all shares of Common Stock of the Company issued at the Closing.

"Thirty-Day Average Trading Price" of the Common Stock on any date shall mean the average of the closing sales prices quoted on the Nasdaq SmallCap Market for the thirty (30) trading days prior to such date.

"Warrants" shall mean the Class G and Class H Warrants described in Section 2.01.

"Warrant Shares" shall mean the shares issuable by the Company upon the exercise of the Warrants.

# ARTICLE II PURCHASE AND SALE OF THE SHARES

- 2.01 Issuance of the Shares and Warrants.
- (a) Shares and Class G Warrant. Subject to the terms and conditions of this Agreement, at the Closing, the Company agrees to issue and sell to Purchaser, and Purchaser agrees to purchase from the Company for an aggregate purchase price of \$3,000,000:
- (1) a number of shares of Common Stock equal to \$3,000,000 divided by the higher of (x) 125% of the Thirty-Day Average Trading Price, and (y) the Five-Day Average Trading Price, with any fractional share amount rounded to the nearest whole share and with 0.5 shares or more rounded up; and
- (2) a warrant to purchase 357,143 shares of Common Stock with an initial exercise price equal to the higher of (x) 115% of the Thirty-Day Average Trading Price, and (y) the Five-Day Average Trading Price, in form and substance satisfactory to the parties (the "Class G Warrant").
- (b) Class H Warrant. Subject to the terms and conditions of this Agreement, at the Closing, the Company agrees to issue to Purchaser a warrant to purchase 320,000 shares of Common Stock with an initial exercise price equal to the higher of (x) the Thirty-Day Average Trading Price, and (y) the Five-Day Average Trading Price and a vesting schedule and otherwise in form and substance satisfactory to the parties (the "Class H Warrant").
  - 2.02 Closing; Delivery of the Shares.
    - (a) Closing.
- (i) The purchase and sale of the Shares and Warrants shall take place at a closing (the "Closing") to be held at the offices of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., 2500 First Union Capitol Center, Raleigh, NC 27601 at 10:00 a.m. Eastern Time on the date of this Agreement, or at such other location, time and date as may be mutually agreed upon by the parties (the "Closing Date"). The Closing shall take place contemporaneously with the execution and delivery of this Agreement and the other Transaction Agreements by the parties thereto.
- (ii) At the Closing, subject to the terms and conditions contained in this Agreement, in payment of the full purchase price for the Shares and the Warrants, Purchaser shall provide a wire transfer of immediately available funds to the Company in an amount equal to Three Million Dollars (\$3,000,000) using the following wire transfer instructions:

Bank Name: First Union National Bank Roanoke, Virginia (USA)

ABA No.: 051400549

Beneficiary: First Clearing Corporation

Account No.:

To further credit Discovery Laboratories, Inc., Account No.

(b) Delivery of Shares and Warrants. At the Closing, the Company shall deliver the Class G Warrant and the Class H Warrant, and as soon as reasonably practicable after the Closing the Company shall deliver a stock certificate evidencing the Shares, all issued in the name of Purchaser and dated as of the Closing Date.

# ARTICLE III CONDITIONS TO CLOSING

- 3.01 Conditions to Purchaser's Obligations at Closing. The obligation of Purchaser to purchase and pay for the Shares and the Warrants at the Closing is subject to each of the following conditions precedent:
- (a) Opinion of Counsel. Dickstein Shapiro Morin & Oshinsky, LLP, counsel to the Company, shall have delivered its legal opinion to Purchaser, in the form acceptable to the parties regarding this Agreement and the transactions contemplated hereby;
- (b) Board Resolutions. Purchaser shall have received at the Closing copies of the resolutions of the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the performance by the Company of all transactions contemplated hereby, certified by an appropriate officer of the Company;
- (c) Officer's Certificate. Purchaser shall have received at the Closing, a certificate, executed by the appropriate officer of the Company and dated as of the Closing Date, together with and certifying (i) the names of the officers of the Company authorized to sign this Agreement together with the true signatures of such officers; (ii) a copy of the certificate of incorporation of the Company, as amended and in effect as of the Closing Date; (iii) a copy of the bylaws of the Company, as amended and in effect as of the Closing Date; (iv) that the representations and warranties contained in Article IV hereof are true and correct as of the Closing Date; and (v) the Company has complied with all the agreements and satisfied all the conditions herein on its part to be performed or satisfied on or prior to the Closing Date;
- (d) Transaction Agreements. Purchaser shall have received at the Closing the Transaction Agreements, duly executed by an authorized officer of the Company; and
- (e) Instruction Letter. The Company shall have transmitted an instruction letter to its stock transfer agent directing it to issue to Purchaser the stock certificate for the Shares, and Purchaser shall have received a copy of such letter.

- 3.02 Conditions to Company's Obligations at Closing. The obligation of the Company to issue and sell the Shares and Warrants at the Closing is subject to each of the following additional conditions precedent:
- (a) Transaction Agreements. The Company shall have received at the Closing the Transaction Agreements, duly executed by an authorized officer of Purchaser or its Affiliates, as the case may be.
- (b) Payment. Purchaser shall have delivered Three Million Dollars (\$3,000,000) in immediately available funds to Company's specified account in accordance with Section 2.02(a)(ii).

# ARTICLE IV REPRESENTATIONS AND WARRANTIES OF COMPANY

The Company represents and warrants to Purchaser as follows:

4.01 Corporate Status. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and the Company is qualified to do business as a foreign corporation in each jurisdiction in which qualification is required, except where failure to so qualify would not have a Material Adverse Effect (as defined herein). Except for Acute Therapeutics, Inc., a wholly owned subsidiary of the Company that is presently inactive, the Company does not own or control, directly or indirectly, any interest in any other corporation, partnership, limited liability company, association, or other business entity. The Company is not a participant in any joint venture, partnership, or similar arrangement. The Company has all requisite corporate power and authority to carry on its business as now conducted.

# 4.02 Authorized Capital Stock.

- (a) As of the Closing Date, 24,753,138 shares of Common Stock and no shares of the Company's preferred stock, par value \$.001 per share ("Preferred Stock"), were issued and outstanding. All of the outstanding shares of the Company's capital stock are duly authorized, validly issued, fully paid and nonassessable.
- (b) Except as set forth on Schedule 4.02(b), there are no outstanding subscriptions, options, warrants, rights, calls, contracts, demands, commitments, conversion rights or other agreements or arrangements of any character or nature whatever under which the Company is or may be obligated (x) to issue or sell shares of its Common Stock or Preferred Stock, or (y) to register shares of its Common Stock or Preferred Stock. No holder of any security of the Company is entitled to any preemptive or similar rights to purchase any securities of the Company.
- (c) The Company has reserved a reasonably adequate number of authorized but unissued shares of Common Stock for issuance upon exercise of the Warrants and such

shares shall remain so reserved (subject to reduction from time to time for Common Stock issued upon the exercise of the Warrants), as long as the Warrants are exercisable.

- 4.03 Issuance, Sale and Delivery of the Securities. The Shares, the Warrants and the Warrant Shares, when issued and paid for pursuant to the terms of this Agreement or the exercise provisions of the Warrants, as the case may be, will be duly and validly authorized, issued and outstanding, fully paid, nonassessable and free and clear of all pledges, liens, encumbrances and restrictions (other than restrictions arising under federal or state securities or "blue sky" laws). The issuance of the Shares, the Warrants and the Warrant Shares by the Company pursuant to this Agreement (hereinafter such securities are sometimes collectively referred to as the "Securities") are not subject to any preemptive or other similar rights. No further approval or authority of the stockholders or the Board of Directors of the Company will be required for the issuance and sale of the Securities to be sold by the Company as contemplated herein. Assuming the accuracy of the representations and warranties of Purchaser contained in Article V, the issuance of the Shares, the Warrants and the Warrant Shares as contemplated by this Agreement is exempt from the registration provisions of the Securities Act.
- 4.04 Due Execution, Delivery and Performance of the Agreements. The Company has full legal right, corporate power and authority to enter into the Transaction Agreements and to perform the transactions contemplated under the Transaction Agreements. The Transaction Agreements have been duly authorized, executed and delivered by the Company. The making and performance of the Transaction Agreements by the Company and the consummation of the transactions contemplated therein will not violate any provision of the organizational documents of the Company, and will not result in the creation of any lien, charge, security interest or encumbrance upon any assets of the Company pursuant to the terms or provisions of, or will not conflict with, result in the breach or violation of, or constitute, either by itself or upon notice or the passage of time or both, a default under any agreement, mortgage, deed of trust, lease, franchise, license, indenture, permit or other instrument to which the Company is a party or by which the Company or its properties may be bound or affected and in each case which would have a material adverse effect on the financial condition, properties, business or results of operations of the Company (a "Material Adverse Effect") or any statute or any authorization, judgment, decree, order, rule or regulation of any court or any regulatory body, administrative agency or other governmental body, applicable to the Company or any of its properties. No consent, approval, authorization or other order of any court, regulatory body, administrative agency or other governmental body, or any other party, is required for the execution and delivery of this Agreement or the consummation of the transactions contemplated by this Agreement. The Transaction Agreements constitute valid and binding obligations of the Company, enforceable in accordance with their respective terms except as such enforceability may be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting the enforcement of creditors' rights generally and as to limitations on the enforcement of the remedy of specific performance and other equitable remedies.
- 4.05 Financial Statements and Reports. Prior to the execution hereof, the Company has made available to Purchaser true and complete copies of the Company's most recently filed Form 10-KSB and the Proxy Statement filed in connection with the Company's most recent annual meeting of stockholders and all Forms 10-QSB and 8-K filed by the Company with the SEC after

- January 1, 2001, in each case without exhibits thereto (the "SEC Reports"). As of their respective filing dates, the SEC Reports were prepared in all material respects in accordance with the requirements of the Securities Act or the Exchange Act, as the case may be, and the rules and regulations of the SEC promulgated thereunder applicable to such SEC Reports. The SEC Reports, when read as a whole, do not contain any untrue statements of a material fact and do not omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The audited consolidated financial statements and unaudited interim financial statements of the Company included in the SEC Reports have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis (except as may be indicated therein or in the notes thereto) and fairly present, in all material respects, the financial position of the Company as at the dates thereof and the results of its operations and cash flows for the periods then ended subject, in the case of the unaudited interim financial statements, to normal year-end adjustments and any other adjustments described in such financial statements. The Company has filed with the SEC on a timely basis, or received a valid extension of such time of filing, all forms, reports and documents required to be filed by it under the Exchange Act.
- 4.06 No Defaults. Except as to defaults, violations and breaches which individually or in the aggregate would not have a Material Adverse Effect on the Company, the Company is not in violation or default of any provision of its certificate of incorporation or bylaws, or other organizational documents, or in breach of or default with respect to any provision of any agreement, judgment, decree, order, mortgage, deed of trust, lease, franchise, license, indenture, permit or other instrument to which it is a party or by which it or any of its properties are bound; and there does not exist any state of fact which, with notice or lapse of time or both, would constitute an event of default or default on the part of the Company as defined in such documents, except such defaults which individually or in the aggregate would not have a Material Adverse Effect on the Company.
- 4.07 Contracts. (a) The contracts and agreements of the Company described in the SEC Reports, including without limitation the Company's licenses and options for licenses, are in full force and effect on the date hereof; and the Company is not, nor to the Company's knowledge is any other party, in breach of or default under any of such contracts or agreements which would have a Material Adverse Effect on the Company. All such contracts and agreements constitute valid and binding obligations of the Company, enforceable in accordance with their respective terms except as such enforceability may be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting the enforcement of creditors' rights generally and as to limitations on the enforcement of the remedy of specific performance and other equitable remedies.
- (b) Without limiting the generality of Section 4.07(a), the Company makes the representations and warranties in this Section 4.07(b) regarding the Sublicense Agreement dated October 28, 1996 (the "Sublicense") among Johnson & Johnson and Ortho Pharmaceutical Corporation, as licensors (collectively, "Licensor"), and Acute Therapeutics, Inc., as licensee, as follows:

- (i) Company is the successor to Acute Therapeutics, Inc. under the Sublicense.
- (ii) The Sublicense is in full force and effect, and the Company is not, nor to the Company's knowledge is the Licensor, in breach or default under the Sublicense in any material respect or in any manner that would permit a party to terminate the Sublicense. To the Company's knowledge, no event or condition exists or has occurred which would permit a party to terminate the Sublicense. The Sublicense is a valid and binding agreement, enforceable in accordance with its terms.
- (iii) To the Company's knowledge, after reasonable investigation and inquiry, (x) the representations and warranties of the Licensor under Section 12 of the Sublicense are true and correct and (y) the Scripps Agreement (as defined in the Sublicense) is in full force and effect.
- (iv) The Company has received a valid and binding extension of the deadline for the filing of the NDA referred to in Section 6 of the Sublicense until October 28, 2002. The Company has achieved all milestones required to be achieved under the Sublicense by the dates required thereunder, taking into account any valid and binding extensions obtained by the Company.
- 4.08 No Actions. There are no legal or governmental actions, suits, proceedings or investigations pending or, to the Company's knowledge, threatened to which the Company is or may be a party or of which property owned or leased by the Company is or may be the subject, or related to environmental or discrimination matters, which actions, suits, proceedings or investigations, individually or in the aggregate, might prevent or might reasonably be expected to have a material adverse affect the transactions contemplated by this Agreement or result in a material adverse change in the financial condition, properties, business, or results of operations of the Company (a "Material Adverse Change"); and no labor disturbance by the employees of the Company exists or is imminent, to the Company's knowledge, which might reasonably be expected to have a Material Adverse Effect. The Company is not a party to or subject to the provisions of any material injunction, judgment, decree or order of any court, regulatory body administrative agency or other governmental body.
- 4.09 Properties. The Company has good and marketable title to all the properties and assets reflected as owned by it in the SEC Reports, subject to no lien, mortgage, pledge, charge or encumbrance of any kind except (i) those, if any, reflected in such SEC Reports, or (ii) those which are not material in amount and do not adversely affect the use made and proposed to be made of such property by the Company. The Company holds its leased properties under valid and binding leases. The Company owns, leases or licenses all such properties necessary for the conduct of its business (as described in the SEC Reports).
- 4.10 No Material Change. Other than the private placement of shares of Common Stock on October 1, 2001, since September 30, 2001, (i) the Company has not incurred any material liabilities or obligations, indirect, or contingent, or entered into any material verbal or written agreement or other transaction which is not in the ordinary course of business or which

could reasonably be expected to result in a material reduction in the future earnings of the Company; (ii) the Company has not sustained any material loss or interference with its business or properties from fire, flood, windstorm, accident or other calamity not covered by insurance; (iii) the Company has not paid or declared any dividends or other distributions with respect to its capital stock and the Company is not in default in the payment of principal or interest on any outstanding debt obligations; (iv) there has not been any change in the capital stock of the Company, other than options issued pursuant to employee equity incentive plans or purchase plans approved by the Company's Board of Directors, or indebtedness material to the Company; and (v) except for the operating losses and negative cash flow the Company has continued to incur, there has not been any Material Adverse Change.

- 4.11 Intellectual Property. (a) The Company owns or has obtained valid rights to use the inventions, patent applications, patents, trademarks (both registered and unregistered), tradenames, copyrights and trade secrets necessary for the conduct of the Company's business (as described in the SEC Reports) (collectively, the "Intellectual Property"); and (b) to the Company's knowledge: (i) there are no third parties who have any ownership rights to any Intellectual Property that is owned by, or has been licensed to, the Company for the product indications described in the SEC Reports that would preclude the Company from conducting its business (as described in the SEC Reports), except for the ownership rights of the owners of the Intellectual Property licensed or optioned by the Company; (ii) there are currently no sales of any products that would constitute an infringement by third parties of any Intellectual Property owned, licensed or optioned by the Company; (iii) there is no pending or threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any Intellectual Property owned, licensed or optioned by the Company; (iv) there is no pending or threatened action, suit, proceeding or claim by others challenging the validity or scope of any Intellectual Property owned, licensed or optioned by the Company; (v) there is no pending or threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary right of others; and (vi) the Company is not subject to any judgment, order, writ, injunction or decree of any court or any Federal, state, local, foreign or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, or any arbitrator, and the Company has not entered into or is a party to any contract which restricts or impairs the use of any such Intellectual Property in a manner which would have a Material Adverse Effect on the Company.
- 4.12 Compliance. The Company has been and is in compliance in all material respects with all applicable laws, rules, regulations and orders, in respect of the conduct of its business and the ownership of its properties, including without limitation with respect to the FFDCA, environmental issues, and taxes and other governmental charges.
- 4.13 Taxes. The Company has filed all federal, state, local and foreign income and other tax returns required to be filed by it and has paid or accrued all taxes shown as due thereon, and the Company has no knowledge of a tax deficiency which has been or might be asserted or threatened against it.
- 4.14 Transfer Taxes. On the Closing Date, all stock transfer or other taxes (other than income taxes) which are required to be paid in connection with the sale and transfer of the Shares

to be sold to the Purchaser hereunder will be, or will have been, fully paid or provided for by the Company and all laws imposing such taxes will be or will have been fully complied with.

- 4.15 Registration and Listing of Stock. The Company's Common Stock is registered pursuant to Section 12(g) of the Exchange Act and is listed on the Nasdaq SmallCap Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or de-listing the Common Stock from the Nasdaq SmallCap Market, nor has the Company received any notification that the SEC or the National Association of Securities Dealers, Inc. (the "NASD") is contemplating terminating such registration or listing.
- 4.16 No Manipulation of Stock. The Company has not taken any action designed to or that might reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the transactions contemplated hereby.
- 4.17 Investment Company. The Company is not an "investment company" or an "affiliated person" of, or "promoter" or "principal underwriter" for an investment company, within the meaning of the Investment Company Act of 1940, as amended.
- 4.18 No Solicitation. The Company has not in the past nor will it hereafter take any action to sell, offer for sale or solicit offers to buy any securities of the Company which would bring the offer, issuance or sale of the Shares, as contemplated by this Agreement, within the provisions of Section 5 of the Securities Act, unless such offer, issuance or sale was or shall be within the exemptions of Section 4 (or other appropriate exemption) of the Securities Act.
- 4.19 Insurance. The Company maintains insurance with sound and reputable insurance companies of the types and in the amounts that the Company reasonably believes is adequate for its business, including, but not limited to, insurance covering all real and personal property owned or leased by the Company against all risks customarily insured against by similarly situated companies, all of which insurance is in full force and effect.
- 4.20 No Integration. Neither the Company nor any of its Affiliates nor any person acting on the Company's behalf has, directly or indirectly, at any time within the past six (6) months made any offer or sale of any security or solicitation of any offer to buy any security under circumstances, that in the opinion of the Company's counsel, concurred by the Purchaser's counsel, would eliminate the availability of the exemption from registration under Regulation D under the Securities Act in connection with the offer and sale of the Securities as contemplated hereby.
- 4.21 No Implied Representations. All of the Company's representations and warranties are contained in this Agreement, and no other representations or warranties by the Company shall be implied.

# ARTICLE V REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Company as follows:

- 5.01 Corporate Status. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of North Carolina. Purchaser has all requisite corporate power and authority to carry on its business as now conducted.
- 5.02 Due Execution, Delivery and Performance of Agreement. Purchaser and its Affiliates have full legal right, corporate power and authority to enter into the Transaction Agreements and to perform the transactions contemplated thereunder. This Agreement has been duly authorized, executed and delivered by Purchaser. This Agreement constitutes the valid and binding obligation of Purchaser enforceable in accordance with its terms.
- 5.03 Investment. Purchaser is acquiring the Securities for Purchaser's own account, and not with a view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the Securities Act. Purchaser acknowledges receiving and reviewing the SEC Reports. Purchaser is aware of the Company's business affairs and financial condition has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the business affairs and financial condition of the Company and (ii) the opportunity to request such additional information which the Company possesses or can acquire without unreasonable effort or expense and has had access to and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Securities to be purchased hereunder. Purchaser, either by reason of its own business or financial experience or the business or financial experience of its professional advisors (who are unaffiliated with and who are not compensated by the Company or any affiliate, finder or selling agent of the Company, directly or indirectly), has such business and financial experience as is required to give it the capacity to utilize the information received, to evaluate the risks involved in purchasing such securities, to make an informed decision about purchasing the Securities and to protect its own interests in connection with the purchase of the Securities and is able to bear the risks of an investment in the Securities. Purchaser is able to bear the economic risk of holding the Securities for an indefinite period of time and can afford a complete loss of its investment. Purchaser is not itself a "broker" or a "dealer" as defined in the Exchange Act and is not an "affiliate" of the Company as defined in Rule 405 promulgated under the Securities Act.
- 5.04 Accredited Investor. Purchaser is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act.
- 5.05 Shares and Warrants Not Registered. Purchaser understands that the Securities are not registered under the Securities Act or registered or qualified under any state securities or "blue sky" laws in reliance on specific exemptions therefrom. Purchaser acknowledges and agrees that (i) it shall not directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the

Securities, except in compliance with the Securities Act and State securities or "blue sky" laws and the rules and regulations promulgated thereunder and with this Agreement, and (ii) neither the Shares, the Warrants nor the Warrant Shares may be resold or otherwise transferred except in a transaction registered under the Securities Act or unless an exemption from such registration is available. Purchaser understands that until the Shares and the Warrant Shares have been registered for resale by the Purchaser in compliance with applicable securities laws, the certificates evidencing the Shares, the Warrants and the Warrant Shares will be imprinted with a legend (in accordance with Section 5.06) that prohibits the transfer of the Shares, the Warrants and the Warrant Shares unless (a) such transaction is registered or such registration is not required or (b) if the transfer is pursuant to an exemption from registration, upon the reasonable request of the Company, an opinion of counsel reasonably satisfactory to the Company is obtained to the effect that the transaction is not required to be registered or is so exempt.

5.06 Legend. To the extent applicable, each certificate evidencing the Shares and the Warrant Shares, shall be endorsed with the legend substantially in the form set forth below:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES OR "BLUE-SKY" LAWS AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED, PLEDGED, ENCUMBERED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER SUCH ACT OR UNDER SUCH LAWS, OR PURSUANT TO AN EXEMPTION FROM SUCH REGISTRATION, AND ARE SUBJECT TO THE TERMS AND CONDITIONS OF THE COMMON STOCK AND WARRANT PURCHASE AGREEMENT DATED DECEMBER 10, 2001, BETWEEN DISCOVERY LABORATORIES, INC. AND PHARMABIO DEVELOPMENT INC., A COPY OF WHICH IS AVAILABLE UPON WRITTEN REQUEST OF THE CORPORATE SECRETARY OF DISCOVERY LABORATORIES, INC."

## ARTICLE VI SUBSCRIPTION RIGHT

6.01 Subscription Right.

(a) If at any time after the date hereof until the date on which there shall no longer remain outstanding at least 25% of the Shares (computed on an as converted to Common Stock basis) purchased by Purchaser under this Agreement, the Company proposes to issue equity securities of the Company of any kind, the primary purpose of which is to raise equity capital (the term "equity securities" shall include for these purposes any warrants, options or other rights to acquire equity securities and debt securities convertible into equity securities), other than (x) to the public in an underwritten offering pursuant to a registration statement filed under the Securities Act, (y) issued in connection with bona fide acquisitions, mergers, joint ventures, collaborative arrangements, strategic alliances or similar transactions, the terms of which are approved by the Company's Board of Directors, or (z) pursuant to any stock option,

stock purchase or similar plan or arrangement for the benefit of the employees of the Company or its subsidiaries, adopted by the Board of Directors, then, the Company shall:

- (i) give written notice to Purchaser (no less than fifteen (15) Business Days prior to the closing of such issuance) setting forth in reasonable detail (A) the designation and all of the terms and provisions of the securities proposed to be issued (the "Proposed Securities"), including, where applicable, the voting powers, preferences and relative participating, optional or other special rights, and the qualification, limitations or restrictions thereof; (B) the price and other terms of the proposed sale of such securities; (C) the amount of such securities proposed to be issued; and (D) such other information as Purchaser may reasonably request in order to evaluate the proposed issuance; and
- (ii) offer to issue and sell to Purchaser, on such terms as the Proposed Securities are issued, upon full payment by Purchaser, a portion of the Proposed Securities equal to a percentage determined by dividing (A) the number of shares of Common Stock then held by Purchaser (computed on an as converted to Common Stock basis but excluding any Warrant Shares attributable to the Class H Warrant that are unvested as of the date thereof), by (B) the total number of shares of Common Stock then outstanding, including for purposes of this calculation all shares of Common Stock issuable upon conversion or exercise in full of any convertible or exercisable securities (other than employee stock options) then outstanding (including shares of Common Stock issuable upon conversion of convertible securities or issuable upon exercise of outstanding warrants).
- (b) Purchaser must exercise its purchase rights hereunder within ten (10) Business Days after receipt of such notice from the Company. The closing of the exercise of such subscription right shall take place simultaneously with the closing of the sale of the Proposed Securities giving rise to such subscription right.
- (c) Upon the expiration of the ten (10) Business Day offering period described above, the Company will be free to sell such Proposed Securities that Purchaser has not elected to purchase during the ninety (90) days following such expiration on financial and economic terms and conditions no more favorable to the purchasers thereof than those offered to Purchaser. Any Proposed Securities offered or sold by the Company after such ninety (90) day period must be reoffered to Purchaser pursuant to this Section 6.01.
- (d) The election by Purchaser not to exercise its subscription rights under this Section 6.01 in any one instance shall not affect its subscription rights as to any subsequent proposed issuance.
- (e) Any sale of such securities by the Company without first giving Purchaser the rights described in this Section 6.01 shall be void and of no force and effect.

#### ARTICLE VII REGISTRATION RIGHTS

#### 7.01 Required Registration.

- (a) At any time following one hundred eighty (180) days after the date of this Agreement, the holders of Registrable Securities who hold and propose to sell Registrable Securities with an aggregate value of at least \$500,000 shall have the right to require the Company to register under the Securities Act on Form S-3 or other comparable or successor form such shares by delivering written notice thereof to the Company. All such registrations shall be non-underwritten. For so long as the Company may be obligated to effect a registration statement pursuant to this Section 7.01, the Company shall use its reasonable best efforts to be and remain eligible to use Form S-3 or other appropriate comparable or successor form under the Securities Act.
- (b) The Company shall be obligated to register Registrable Securities pursuant to this Section 7.01 on not more than one occasion during any twelve-month rolling period, or on more than two occasions in the aggregate; provided, however, that such obligation shall be deemed satisfied only when a registration statement covering all shares of Registrable Securities requested to be included in such registration statement by the holders thereof, for sale in accordance with the method of disposition specified by the requesting holders, shall have become effective or if the holders participating in the registration withdraw from the registration; provided, further, that if such registration statement has become effective but the contemplated public offering is withdrawn prior to the completion thereof, or if holders participating in the registration withdraw, causing the requirements of this Section not to be met, because of material adverse developments affecting the Company that were not known to the participating holders prior to such effectiveness, then such registration shall not count as one of the registrations hereunder.
- (c) The Company shall be entitled to include in any registration statement referred to in this Section 7.01, for sale in accordance with the method of disposition specified by requesting holders, shares of Common Stock to be sold by the Company for its own account or for the account of other security holders of the Company, but only to the extent that such inclusion will not adversely affect the offering for the account of the holders of Registrable Securities.
- 7.02 Incidental Registration. If the Company at any time (other than pursuant to Section 7.01) proposes to register any of its securities under the Securities Act for sale to the public, whether for its own account or for the account of other security holders or both (except with respect to registration statements on Forms S-4, S-8 or another form not available for registering the Registrable Securities for sale to the public, or which relate to employee benefit plans or with respect to corporate reorganizations or other transactions subject to Rule 145 of the Securities Act), each such time it will give written notice to all holders of outstanding Registrable Securities of its intention so to do. Upon the written request of any such holder, received by the Company within thirty (30) days after the giving of any such notice by the Company, to register

any of its Registrable Securities, the Company will use its best efforts to cause such Registrable Securities to be included in the registration statement proposed to be filed by the Company, all to the extent requisite to permit the sale or other disposition of such Registrable Securities so registered. In the event that any registration pursuant to this Section 7.02 shall be an underwritten public offering of Common Stock, the number of shares of Registrable Securities to be included in such an underwriting may be limited if and to the extent that the managing underwriter shall be of the opinion that such inclusion would adversely affect the marketing of the securities to be sold by the Company therein, and, in such case, the number of shares of securities that are entitled to be included in the registration and underwriting shall be allocated in the following manner: The securities of the Company held by officers, directors and other stockholders of the Company, other than securities held by holders ("Demand Holders") who have contractual rights (existing prior to the date of this Agreement) to participate in or demand such registration, shall be excluded from such registration and underwriting to the extent required by such limitation, and, if a limitation on the number of shares is still required, the number of shares that may be included in the registration and underwriting by each of the holders Registrable Securities and Demanding Holders shall be reduced, on a pro rata basis (based on the number of shares held by such holders of Registrable Securities and Demanding Holders), by such minimum number of shares as is necessary to comply with such limitation.

- 7.03 Registration Procedures. If and whenever the Company is required by the provisions of Section 7.01 or 7.02 to effect the registration of any Registrable Securities under the Securities Act, the Company will, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a registration statement with respect to such securities as soon as reasonably practicable after delivery of the applicable notice, and in any event within thirty (30) days thereof, and use its reasonable best efforts to cause such registration statement to become effective within ninety (90) days after delivery of such notice and remain effective for the period of the distribution contemplated thereby (determined as hereinafter provided); provided, however, that that Company's obligation to file a registration statement, or cause such registration statement to become and remain effective, shall be suspended for a period not to exceed ninety (90) days in any twelve-month period if in the reasonable judgment of the Company's Board of Directors it would be detrimental to the Company to effect a registration at such time;
- (b) prepare and file with the SEC such amendments and supplements to such registration statement and the related prospectus as may be necessary to keep such registration statement effective for the period specified in paragraph (a) above and comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement in accordance with the sellers' intended method of disposition set forth in such registration statement for such period; provided, however, the holders hereby acknowledge that the Company may notify the holders of the suspension of the use of the prospectus forming a part of the registration statement until such time as an amendment to such registration statement has been filed by the Company and declared effective by the SEC or until the Company has otherwise amended or supplemented such prospectus, and upon receipt of such notice the holders shall suspend the use of the prospectus and shall not offer

or sell any securities pursuant to said prospectus during the period commencing at the time at which the Company gives the holders notice of the suspension of the use of said prospectus and ending at the time the Company gives the holders notice that holders may thereafter effect sales pursuant to said prospectus. Notwithstanding anything herein to the contrary, the Company (i) shall not suspend use of the registration statement by holders unless such suspension is in the good faith opinion of the Company and its counsel advisable under the federal securities laws and the rules and regulations promulgated thereunder; and (ii) shall use its best efforts to amend to such registration statement or amend or supplement such prospectus as soon as practicable to again permit sales pursuant to said prospectus;

- (c) furnish to each seller of Registrable Securities and to each underwriter, if applicable, such number of copies of the registration statement and the prospectus included therein (including each preliminary prospectus) as such persons reasonably may request in order to facilitate the public sale or other disposition of the Registrable Securities covered by such registration statement;
- (d) use its best efforts to register or qualify the Registrable Securities covered by such registration statement under the securities or "blue sky" laws of such jurisdictions as the sellers of Registrable Securities or, in the case of an underwritten public offering, the managing underwriter reasonably shall request, provided, however, that the Company shall not for any such purpose be required to qualify generally to transact business as a foreign corporation in any jurisdiction where it is not so qualified or to consent to general service of process in any such jurisdiction;
- (e) immediately notify each seller of Registrable Securities and each underwriter, if applicable, under such registration statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event of which the Company has knowledge as a result of which the prospectus contained in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances then existing; and
- (f) if the offering is underwritten and at the request of any seller of Registrable Securities, use its best efforts to furnish on the date that Registrable Securities are delivered to the underwriters for sale pursuant to such registration: (i) an opinion dated such date of counsel representing the Company for the purposes of such registration, addressed to the underwriters and to such seller, in form and substance as is customarily given in an underwritten public offering; and (ii) a letter dated such date from the independent public accountants retained by the Company, addressed to the underwriters and to such seller, in form and substance as is customarily given in an underwritten public offering.

For purposes of Section 7.03(a) and (b), the period of distribution of Registrable Securities in any registration shall be deemed to extend until the earlier of the sale of all Registrable Securities covered thereby and one hundred twenty (120) days after the effective date thereof.

7.04 Expenses. All expenses incurred by the Company in complying with Sections 7.01, 7.02 and 7.03, including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of counsel and independent public accountants for the Company, fees and expenses (including counsel fees) incurred in connection with complying with state securities or "blue sky" laws, fees of the NASD, transfer taxes, fees of transfer agents and registrars and the reasonable fees and disbursements of one counsel for the sellers of Registrable Securities (not to exceed \$25,000 in the aggregate), but excluding any Selling Expenses, are called "Registration Expenses". All underwriting discounts and selling commissions applicable to the sale of Registrable Securities are called "Selling Expenses". The Company will pay all Registration Expenses in connection with each registration statement under Section 7.01 or 7.02. All Selling Expenses in connection with each such registration statement shall be borne by the participating sellers on a pro rata basis based on the number of Registrable Securities included in such registration statement.

#### 7.05 Indemnification and Contribution.

(a) In the event of a registration of any of the Registrable Securities under the Securities Act pursuant to Section 7.01 or 7.02, to the extent permitted by applicable law, the Company will indemnify and hold harmless each seller of such Registrable Securities thereunder, each underwriter of such Registrable Securities thereunder and each other person, if any, who controls such seller or underwriter within the meaning of Section 5 of the Securities Act, against any losses, claims, damages or liabilities, joint or several, to which such seller, underwriter or controlling person may become subject under the Securities Act or other applicable Federal or State securities or "blue sky" laws, to the extent that such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any registration statement under which such Registrable Securities were registered under the Securities Act, any preliminary prospectus or final prospectus contained therein, or any amendment or supplement thereof, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse each such seller, each such underwriter and each such controlling person for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable, to any such indemnitee if and to the extent that any such loss, claim, damage or liability arises out of or is based upon an (i) untrue statement or alleged untrue statement or omission or alleged omission so made in conformity with information furnished by or on behalf of such indemnitee in writing specifically for use in such registration statement or prospectus or (ii) such untrue statement or alleged untrue statement or omission or alleged omission was contained in a preliminary or earlier effective prospectus and corrected in a final or amended prospectus, and such holder of Registrable Securities failed to deliver a copy of the final or amended prospectus at or prior to the confirmation of the sale of the Registrable Securities to the buyer of such Registrable Securities; provided, further, that the indemnity agreement contained in this Section 7.05(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, provided that such consent shall not be required if the settlement shall

include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such claim or litigation.

- (b) In the event of a registration of any of the Registrable Securities under the Securities Act pursuant to Section 7.01 or 7.02, to the extent permitted by applicable law, each seller of such Registrable Securities thereunder, severally and not jointly, will indemnify and hold harmless the Company, each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act, each officer of the Company who signs the registration statement, each director of the Company, each underwriter and each person who controls any underwriter within the meaning of the Securities Act, against all losses, claims, damages or liabilities, joint or several, to which the Company or such officer, director, underwriter or controlling person may become subject under the Securities Act or other applicable Federal or State securities or "blue sky" laws, to the extent that such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in the registration statement under which such Registrable Securities was registered under the Securities Act, any preliminary prospectus or final prospectus contained therein, or any amendment or supplement thereof, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse the Company and each such officer, director, underwriter and controlling person for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that such seller will be liable hereunder in any such case if and only to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information pertaining to such seller, as such, furnished in writing to the Company by or on behalf of such seller specifically for use in such registration statement or prospectus, and provided, further, that the indemnity agreement contained in this Section 7.05(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of such seller, which consent shall not be unreasonably withheld, provided that such consent shall not be required if the settlement shall include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such claim or litigation; provided, further, that the liability of each seller hereunder shall be limited to the net proceeds received for the account of such seller from the sale of Registrable Securities covered by such registration statement.
- (c) Promptly after receipt by an indemnified party hereunder of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party hereunder, notify the indemnifying party in writing thereof, but the omission so to notify the indemnifying party shall not relieve it from any liability which it may have to such indemnified party other than under this Section 7.05 and shall only relieve it from any liability which it may have to such indemnified party under this Section 7.05 if and to the extent the indemnifying party is prejudiced by such omission. In case any such action shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in and, to the

extent it shall wish, to assume and undertake the defense thereof with counsel reasonably satisfactory to such indemnified party, and, after notice from the indemnifying party to such indemnified party of its election so to assume and undertake the defense thereof, the indemnifying party shall not be liable to such indemnified party under this Section 7.05 for any legal expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation and of liaison with counsel so selected, provided, however, that, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be reasonable defenses available to it which are different from or additional to those available to the indemnifying party or if the interests of the indemnified party reasonably may be deemed to conflict with the interests of the indemnifying party, the indemnified party shall have the right to select a separate counsel and to assume such legal defenses and otherwise to participate in the defense of such action, with the reasonable expenses and fees of such separate counsel and other expenses related to such participation to be reimbursed by the indemnifying party as incurred; provided, further, that the Company shall not have any reimbursement obligation for the expenses and fees of more than one such separate counsel for all indemnitees.

(d) In order to provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any holder of Registrable Securities exercising rights under this Agreement, or any controlling person of any such holder, makes a claim for indemnification pursuant to this Section 7.05 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 7.05 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any such selling holder or any such controlling person in circumstances for which indemnification is provided under this Section 6; then, and in each such case, the Company and such holder will contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other, as well as any other relevant equitable considerations. The relative fault of the parties shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case, (A) no such holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered by it pursuant to such registration statement; and (B) no person or entity guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person or entity who was not guilty of such fraudulent misrepresentation.

7.06 Changes in Common Stock. If, and as often as, there is any change in the Common Stock by way of a stock split, stock dividend, combination or reclassification, or through a merger, consolidation, reorganization or recapitalization, or by any other means,

appropriate adjustment shall be made in the provisions hereof so that the rights and privileges granted hereby shall continue with respect to the Common Stock as so changed.

- 7.07 Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the SEC that may at any time permit the sale of the Registrable Securities to the public without registration, the Company agrees to:
- (a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;
- (b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and
- (c) furnish to each holder of Registrable Securities forthwith upon request a written statement by the Company as to its compliance with the reporting requirements of such Rule 144 and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed by the Company as such holder may reasonably request in availing itself of any rule or regulation of the SEC allowing such holder to sell any Registrable Securities without registration.
- 7.08 Future Registration Rights. The Company shall not, except with the consent of the holders of a majority of the Registrable Securities, enter into any agreement with any holder or prospective holder of any securities of the Company that would allow such holder or prospective holder to include such securities in any registration filed pursuant to Section 7.01 or 7.02 hereof, unless under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion thereof will not reduce the amount of Registrable Securities that is included.
- 7.09 Certain Holder Obligations. (a) As a condition to the inclusion of its Registrable Securities in a registration effected pursuant to Section 7.01 or 7.02, the holders will promptly provide the Company with such information as the Company shall reasonably request in order to prepare the applicable registration statement for such registration, including, but not limited to, information regarding the holders, the securities of the Company owned beneficially or of record by the holders, the distribution proposed by the holders, a customary selling securityholders questionnaire and, upon the Company's request, the holders shall provide such information in writing and signed by the holders and stated to be specifically for inclusion in the applicable registrations. In the event that the distribution of the Common Stock covered by the applicable registration statement shall be effected pursuant to an underwritten offering as contemplated by Section 7.02, the inclusion of the Registrable Securities shall be conditioned on the holders' execution and delivery of a customary underwriting agreement with terms and conditions reasonably satisfactory to the Company with respect thereto.
- (b) The holders shall not take any action with respect to any distribution deemed to be made pursuant to any registration statement pursuant to Section 7.01 or 7.02, which would constitute a violation of Regulation M under the Exchange Act.

- (c) If, at the end of any period during which the Company is obligated to keep a registration statement pursuant to Section 7.01 or 7.02 effective, the holders have Registrable Securities which were included in such registration statement, the holders shall discontinue sales of such securities pursuant to the registration statement and prospectus upon receipt of notice from the Company of its intention to remove from registration the shares covered by registration statement which remain unsold (as permitted under the provisions of this Article VII, and the holders shall notify the Company of the number of shares registered which remain unsold promptly upon receipt of such notice from the Company.
- (d) The holders shall have no right to take any action to restrain, enjoin or otherwise delay any registration as a result of any controversy that may arise with respect to the interpretation or implementation of the terms of this Article VII.
- 7.10 Termination of Registration Rights. The obligations of the Company to register shares of Registrable Securities under Section 7.01 or 7.02 for a holder of Registrable Securities shall terminate on the earlier to occur of (i) the date on which such holder can, in the reasonable opinion of counsel to the Company, sell all shares of its Registrable Securities in a three-month period without registration under the Securities Act pursuant to Rule 144 under the Securities Act.
- 7.11 Listing. The Company shall use its best efforts to list, and keep authorized for listing, the Registrable Securities on the Nasdaq SmallCap Market, the Nasdaq National Market or any national securities exchange on which the Common Stock is traded.

# ARTICLE VIII ADDITIONAL AGREEMENTS

- 8.01 Short Sales, etc. Purchaser represents and agrees that, during the period from October 3, 2001 through the date of this Agreement, Purchaser and its Affiliates did not and, from the date hereof until the first anniversary of the date of this Agreement, Purchaser will not, and shall cause its Affiliates not to, execute or effect or cause to be executed or effected any "short sale" (as defined in Rule 3b-3 of the Exchange Act) of Common Stock or any hedging transaction in which the other party to such transaction is reasonably likely to engage in such a short sale as a direct result of such transaction.
- 8.02 Restriction on Purchase of Common Stock. Until the expiration or termination of the Commercialization Agreement, Purchaser will not, and shall cause its Affiliates not to, purchase or become the beneficial owner of any shares of Common Stock which results in Purchaser and its Affiliates beneficially owning more than nineteen percent (19%) of the issued and outstanding shares of Common Stock; provided, however that (a) nothing in this Section shall prevent Purchaser and its Affiliates from acquiring Common Stock contemplated by the Transaction Agreements and (b) Purchaser shall not be deemed to violate this Section as a result of any reorganization, recapitalization, stock repurchase, stock combination or other similar transaction effected by the Company with respect to the Common Stock if Purchaser and its

Affiliates beneficially owned less than 19% of the issued and outstanding shares of Common Stock before giving effect to such transaction.

- 8.03 Restrictions on Sale of Shares.
- (a) Until [\*\*\*] after the date of this Agreement, Purchaser will not sell or otherwise transfer the Shares.
- (b) If, at any time prior to the first anniversary of the date of this Agreement, Purchaser proposes to sell Shares constituting [\*\*\*] or more of the outstanding shares of Common Stock, then Purchaser shall first offer to sell such Shares of the Company, and the parties agree to negotiate in good faith to reach an agreement on the purchase price and other terms of the sale of such Shares to the Company. If the parties are not able to reach such an agreement within ten (10) Business Days, then Purchaser shall be free to proceed with such sale to a third party so long as it complies with any other applicable terms of this Agreement.
- (c) Until the expiration or termination of the Commercialization Agreement, Purchaser will not knowingly sell the Shares to a person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product which directly competes with the Product (as defined in the Investment and Commission Agreement) for any of the indications contemplated by the Transaction Agreements on the date hereof. In any event, this subsection (c) shall not prevent Purchaser from selling the Shares in open-market transactions.
- (d) The restrictions under this Section shall not be applicable to any transfers of the Shares to any Affiliate of Quintiles Transnational Corp., so long as such Affiliate agrees in an enforceable written instrument to be bound by all the terms and conditions of this Agreement as if it were Purchaser and a party hereto, which instrument shall be delivered a reasonably practicable time prior to such sale or transfer.
- 8.04 Voting Agreement. Until the earlier of (i) such time that Purchaser beneficially owns less than [\*\*\*] of the issued and outstanding shares of Common Stock of the Company, and (ii) the completion of the Company's annual meeting of shareholders for the calendar year [\*\*\*], at each annual meeting of the shareholders of the Company or in connection with any other meeting or action by written consent in lieu of a meeting of the shareholders of the Company, Purchaser shall vote or act with respect to all shares of Common Stock beneficially owned by it (x) in favor of all persons nominated by the then current Board of Directors of the Company for election to the Board of Directors of the Company and (y) in accordance with the recommendations of the Board of Directors with respect to any other issue; provided, that this clause (y) shall not apply to any issue that is directly related to the matters which are subject to the Transaction Agreements or to any Change of Control (as defined in the Loan Agreement). The voting agreement contained in this Section 8.04 is irrevocable to the extent permitted by applicable law and is coupled with an interest. Until the earlier of (i) such time that Purchaser

beneficially owns less than [\*\*\*] of the issued and outstanding shares of Common Stock of the Company, and (ii) [\*\*\*] years after the date of this Agreement, at and in relation to each annual meeting of the shareholders of the Company or in connection with any other meeting or action by written consent in lieu of a meeting of shareholders of the Company, Purchaser will not actively oppose any items referred to in clauses (x) and (y) above.

8.05 Continuation of Certain Restrictions. If at any time prior to the [\*\*\*] anniversary of the date of this Agreement, Purchaser transfers Shares in accordance with the provisions of this Agreement, Purchaser shall not effect such transfer unless the transferee agrees in an enforceable written instrument to be bound by the terms and conditions of Sections 8.01, 8.03(c), and 8.04; provided, however, that (i) such transferee shall not be bound to any greater extent as to duration of time or otherwise than Purchaser is bound under such Sections on the date of this Agreement and (ii) this Section 8.05 shall not apply to any transfer by Purchaser to a transferee that will own one percent or less of the Company's outstanding shares of Common Stock after giving effect to such transfer.

8.06 Termination of Restrictions. Upon the occurrence of an Event of Default under the Loan Agreement or the termination of the Investment and Commission Agreement by Purchaser in accordance with its terms, all of the provisions of this Article VIII shall immediately terminate and have no further force or effect.

## ARTICLE IX MISCELLANEOUS

- 9.01 Amendments, Etc. No amendment or waiver of any provision of this Agreement, nor consent to any departure by the Company therefrom, shall in any event be effective unless the same shall be in writing and signed by Purchaser, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.
- 9.02 Notices. All notices and other communications provided for hereunder shall be in writing, shall specifically refer to this Agreement, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder, and shall be deemed to have been sufficiently given for all purposes if (a) mailed by first class certified or registered mail, postage prepaid, (b) sent by nationally recognized overnight courier for next Business Day delivery, (c) personally delivered, or (d) made by telecopy or facsimile transmission with confirmed receipt.

If to Company: Discovery Laboratories, Inc.

350 South Main Street, Suite 307

Doylestown, PA 18901-4874

Attn: President

Facsimile: (215) 340-3940

with a copy to:

Roberts, Sheridan & Kotel The New York Practice of

Dickstein Shapiro's Corporate & Finance Group

1177 Avenue of the Americas, 41st Floor

New York, NY 10036-2714

Attn: Ira L. Kotel Facsimile: (212) 997-9880

If to Purchaser: PharmaBio Development Inc.

> 4709 Creekstone Drive Suite 200 Riverbirch Bldg.

Durham, NC 27703 Attn: President

Facsimile: (919) 998-2090

Smith, Anderson, Blount, Dorsett with a copy to:

Mitchell & Jernigan, L.L.P. 2500 First Union Capitol Center

Raleigh, NC 27601

Attn: Christopher B. Capel Facsimile: (919) 821-6800

9.03 No Waiver; Remedies. No failure on the part of Purchaser to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.

9.04 Attorneys' Fees. In the event that any dispute among the parties to this Agreement should result in litigation, the prevailing party in such dispute shall be entitled to recover from the losing party all fees, costs and expenses enforcing any right of such prevailing party under or with respect to this Agreement, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all fees, costs and expense of appeals.

9.05 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of the Company and Purchaser and their respective successors and assigns, provided that neither the Company nor Purchaser may assign or transfer any or all of its rights or obligations under this Agreement without the prior written consent of the other party and any

attempted assignment without such consent shall be null and void; provided, however, that Purchaser may at any time assign or transfer any of its rights or obligations under this Agreement to an Affiliate.

- 9.06 Severability. To the extent any provision of this Agreement is prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.
- 9.07 Entire Agreement. This Agreement and the other Transaction Agreements embody the entire agreement and understanding between the parties hereto with respect to the subject matter thereof and supersede all prior oral or written agreements and understandings relating to the subject matter thereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in the Transaction Agreements shall affect, or be used to interpret, change or restrict, the express terms and provisions of the Transaction Agreements.
- 9.08 Further Action. Each party shall, without further consideration, take such further action and execute and deliver such further documents as may be reasonably requested by the other party in order to carry out the provisions and purposes of this Agreement.
- 9.09 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which, when taken together, shall constitute one and the same instrument. This Agreement may be executed and delivered by telecopy or facsimile transmission and any execution by such means shall be deemed an original.
- 9.10 Survival. The representations, warranties, covenants and agreements made herein by the Company and Purchaser shall survive the Closing.
- 9.11 Publicity. Except as otherwise required by applicable law or by obligations pursuant to any listing agreement with or rules of any securities exchange or automated quotation system, each party shall, and shall cause its respective Affiliates to, not, issue any press release or make any other public statement relating to, connected with or arising out of this Agreement or the matters contained herein without the other parties' prior written approval of the contents and the manner of presentation and publication thereof (which approval shall not be unreasonably withheld or delayed).
- 9.12 Governing Law. This Agreement, including, without limitation, the interpretation, performance, enforcement, breach or termination thereof and any remedies relating thereto, shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, as applied to agreements executed and performed entirely in the State of Delaware, without regard to conflicts of law rules.
- 9.13 Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or

information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the JCC (as defined in the Commercialization Agreement), which will use its good faith efforts to resolve the Dispute within ten (10) days. If the JCC is unable to resolve the Dispute in such period, the JCC will refer the Dispute to the Chief Executive Officers of the Company and Purchaser. For all Disputes referred to the Chief Executive Officers, the Chief Executive Officers shall use their good faith efforts to meet at least two times in person and to resolve the Dispute within ten (10) days after such referral.

- 9.14 Arbitration. (a) If the parties are unable to resolve any Dispute under Section 9.13, then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 9.14. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.
- (b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by the Company, one by Purchaser, and the third by the two so chosen. If both or either of the Company or Purchaser fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this agreement, and any such party need not comply with the procedural provisions of this Section 9.14 in order to assert such counterclaim(s).
- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in Wilmington, Delaware or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60) day period. In addition, the following rules and procedures shall apply to the arbitration:
- (e) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 9.14.

- (f) The decision of the arbitrators, which shall be in writing and state the findings the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.
- (g) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.
- (h) The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 9.14, and the costs of the arbitrator(s) shall be equally divided between the parties; provided, however, that each party shall bear the costs incurred in connection with any Dispute brought by such party that the arbitrators determine to have been brought in bad faith.
- (i) Except as provided in the last sentence of Section 9.14(a), the provisions of this Section 9.14 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising with regard to this Agreement. Any party commencing a lawsuit in violation of this Section 9.14 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.
- 9.15 HSR Filings. Purchaser acknowledges and agrees that if any of the transactions contemplated by this Agreement or any other Transaction Agreement shall require compliance with any applicable requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the "HSR Act"), and the antitrust, competition, foreign investment or similar laws of any foreign countries or supranational commissions or boards that require pre-merger notifications or filings by either the Company or Purchaser, neither party shall have breached in any material respect its obligations under this Agreement if the closing of any such transaction is delayed to allow the parties to comply with any such laws, rules and regulations, and any waiting periods required thereunder, including, but not limited to compliance with any "Second Requests" as provided for, and defined in, the HSR Act.

[signature page follows]

[Signature Page to Common Stock and Warrant Purchase Agreement]

IN WITNESS WHEREOF, Company and Purchaser have caused this Common Stock and Warrant Purchase Agreement to be executed in their names by their duly authorized officers or representatives effective as of the date first above written.

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

-----

David L. Lopez

Vice President and General Counsel

PHARMABIO DEVELOPMENT INC.

By: /s/ Thomas C. Perkins

Thomas C. Perkins

Vice President and General Counsel

Portions of this Exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions, marked by [\*\*\*], have been separately filed with the Securities and Exchange Commission.

#### LOAN AGREEMENT

THIS LOAN AGREEMENT (this "Agreement") is dated and entered into as of December 10, 2001 (the "Effective Date") by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender").

WHEREAS, Borrower and Lender are parties to the Common Stock and Warrant Purchase Agreement dated as of the date hereof (the "Purchase Agreement") and the Investment and Commission Agreement dated as of the date hereof (the "Investment and Commission Agreement");

WHEREAS, Borrower and Quintiles Transnational Corp., an Affiliate of Lender ("Quintiles"), are parties to a Commercialization Agreement (the "Commercialization Agreement"), dated as of the date hereof;

WHEREAS, in connection with the Purchase Agreement, Investment and Royalty, and Commercialization Agreement, Lender is willing to extend certain credit facilities to Borrower, subject to and upon the terms and conditions of this Agreement; and

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties hereby agree as follows:

## ARTICLE I DEFINITIONS

1.01 Definitions. Capitalized terms used but not defined in the text of this Agreement shall have the meanings ascribed to them on Exhibit A attached hereto and incorporated herein by reference.

# ARTICLE II Amount and Terms of Loan

### 2.01 Advances.

(a) Subject to and upon the terms and conditions set forth herein, Lender agrees, at any time and from time to time, from and after the occurrence of Milestone One (as defined below) and prior to December 10, 2004 (the "Maturity Date"), to make advances (each an

1

"Advance" and collectively the "Advances") to Borrower at such times and in such amounts as Borrower shall request pursuant to this Agreement, up to an aggregate principal amount of Eight Million, Five Hundred Thousand Dollars (\$8,500,000) (as adjusted and subject to the satisfaction of certain milestones in accordance with this Section 2.01, the "Commitment") in lawful money of the United States of America in immediately available funds. The Commitment shall become available to Borrower as follows:

- (i) Upon the occurrence of Milestone One (as defined below), one third (1/3) of the Commitment shall be available. "Milestone One" shall mean the later to occur of (i) the completion by The Lewin Group of a market opportunity assessment and report in customary form regarding the Product, which shall include without limitation an assessment and report as to pre-launch commercialization requirements and sales forecasts, and (ii) Borrower shall have obtained a valid and binding extension of the deadline for the filing of the NDA referred to in Section 6 of the License Agreement until at least October 28, 2003.
- (ii) Upon the occurrence of Milestone One and Milestone Two (as defined below), two thirds (2/3) of the Commitment shall be available. "Milestone Two" shall mean the earlier to occur of (i) the sale after the date of this Agreement by Borrower of shares of its capital stock for cash proceeds with an aggregate purchase price of at least \$10,000,000 in one or more capital financing transactions or pursuant to the exercise of options, warrants or rights to purchase its capital stock, and in each case the proceeds of which may be used for general corporate purposes or (ii) the

public disclosure by Borrower of Phase III clinical trial data regarding the indication for the Product known as idiopathic respiratory distress syndrome ("IRDS"), and the completion by Quintiles or an appropriate Affiliate of a written assessment and report indicating that such data is favorable and that such data substantially enhances the Company's prospects with respect to its ability to repay the Commitment as increased by such Milestone Two.

(iii) Upon the occurrence of Milestone One, Milestone Two, and Milestone Three (as defined below), the full Commitment shall be available. "Milestone Three" shall mean the earlier to occur of (i) the completion by Quintiles or an appropriate Affiliate of a written assessment and report in customary form indicating the "approvability" by the FDA of Borrower's NDA for the Product for either the IRDS indication or the indication known as meconium aspiration syndrome ("MAS"), which shall include without limitation an assessment and report as to the quality of the documentation comprising such NDA and the clinical data included in such NDA, or (ii) the issuance by the FDA of a letter in customary form indicating that Borrower's NDA for the Product is "approvable" with respect to Borrower's NDA for either the IRDS indication or the MAS indication.

(b) Notwithstanding anything to the contrary in this Agreement, upon the occurrence of the "First Milestone" (as defined in the Investment and Commission Agreement),

Borrower shall prepay Advances as described in Section 2.05(b), and the Commitment shall be automatically reduced by the amount of such required prepayment.

- (c) Notwithstanding anything to the contrary in this Agreement, upon the occurrence of the "Second Milestone" (as defined in the Investment and Commission Agreement), Borrower shall prepay the aggregate outstanding amount of all Advances and the Commitment shall be automatically terminated.
- (d) As contemplated by the Commercialization Agreement, the JCC (as defined therein) may authorize expenditures for pre-Launch Marketing Services in excess of \$8,500,000 up to \$10,000,000 (without the consent of Lender). In the event that the JCC authorizes such expenditures in excess of \$8,500,000 (but not in excess of \$10,000,000), (i) the Commitment shall be deemed increased by a commensurate amount, but in any event not in excess of a maximum Commitment of \$10,000,000 in the aggregate, and (ii) Borrower shall execute a new promissory note as described in Section 3.02(e).
- (e) In the event that the parties mutually agree to authorize expenditures for pre-Launch Marketing Services in excess of \$10,000,000 (but not in excess of \$15,000,000), (i) the Commitment shall be deemed increased by a commensurate amount, and (ii) Borrower shall execute a new promissory note as described in Section 3.02 (e). Notwithstanding anything in this Agreement to the contrary, any increase in the Commitment in excess of \$10,000,000 shall require the express written agreement of Lender in the sole discretion of Lender, and this subsection (e) shall not imply that Lender is willing, or obligate Lender in any manner, to agree to any such increase or to agree to any increase in Lender's obligations under the Investment and Commission Agreement, with any such increase in Lender's obligations being required to be set forth in an express written agreement referring to the Investment and Commission Agreement.
- (f) Borrower may use the Commitment, as in effect from time to time, on a revolving basis by borrowing, repaying the Advances in whole or in part, and reborrowing, all in accordance with the terms and conditions of this Agreement. The aggregate outstanding amount of the Advances at any time shall not exceed the Commitment as in effect at such time. If at any time, the aggregate outstanding principal amount of the Advances exceeds the Commitment, Borrower shall immediately pay to Lender in cash the amount of such excess.
- (g) Each Advance shall be a principal amount of a loan, evidenced by the Note referred to below.
- 2.02 Use of Proceeds. At least [\*\*\*] of the Advances shall be used for the payment of pre-Launch Marketing Services (as defined in the Commercialization Agreement) provided by Quintiles Transnational Corp. or its Affiliates and the remainder of the Advances may be used for general corporate purposes.

- 2.03 Notices of Advances; Disbursement of Funds.
- (a) Whenever Borrower desires to obtain an Advance, Borrower shall give to Lender a written notice of the requested Advance, signed by an authorized officer of Borrower (each a "Notice of Advance"), and received no later than 3:00 p.m. Eastern Time three (3) Business Days before the day on which Borrower desires the Advance to be made. The Notice of Advance shall specify: (i) the aggregate principal amount of the Advance to be made; (ii) the date on which Borrower desires the Advance to be made, which date shall be a Business Day; and (iii) an account of Borrower to which the Advance shall be directed and wire transfer instructions. The giving of each Notice of Advance shall constitute a representation and warranty by Borrower to Lender that the conditions precedent set forth in Section 3.02 have been satisfied.
- (b) Whenever Borrower desires to obtain an Advance, Lender shall make available to Borrower, at an account of Borrower specified to Lender, not later than 2:00 p.m. Eastern Time on the date specified in the applicable Notice of Advance the aggregate amount of such requested Advance. Each such payment shall be an Advance under this Agreement and the Note. Each Notice of Advance requesting an Advance shall be irrevocable when sent by Borrower, unless otherwise agreed by Lender.
  - (c) The amount of each Advance shall not be less than [\*\*\*].
- 2.04 Note. Borrower's obligation to pay the principal of, and interest on, the Advances made by Lender shall be evidenced by a single promissory note (the "Note") duly executed and delivered by Borrower in the form of Exhibit B attached hereto. All Advances made by Lender to Borrower, and all payments in respect thereof (and all reborrowings thereof, if any), shall be recorded by Lender and shall be endorsed on the grid attached to the Note. Failure to make any such notation shall not affect Borrower's obligations in respect of such Advances.
  - 2.05 Repayment; Interest; Fees.
- (a) Borrower shall pay the aggregate outstanding principal amount of, and all accrued interest on, all Advances on or before the Maturity Date, unless due and payable sooner pursuant to the provisions of this Agreement. Borrower may prepay any Advance or any accrued interest on Advances at any time and from time to time without penalty, on the following terms and conditions: (i) Borrower shall give Lender at least three (3) Business Days' prior notice of its intent to prepay and the amount of the prepayment and (ii) each prepayment shall not be less than [\*\*\*].
- (b) Upon the occurrence of the "First Milestone" (as defined in the Investment and Commission Agreement), Borrower shall prepay the Advances in an aggregate principal amount equal to seventy percent (70%) of the aggregate amount of the outstanding Advances.

- (c) Upon the occurrence of the "Second Milestone" (as defined in the Investment and Commission Agreement), Borrower shall prepay the aggregate outstanding amount of all Advances.
- (d) Borrower agrees to pay interest in respect of the outstanding principal amount of each Advance from the date the proceeds are made available to Borrower until repaid. Interest on the outstanding principal amount of each Advance shall accrue and be payable at a rate per annum (the "Base Rate") equal to the greater of (i) [\*\*\*] or (ii) [\*\*\*] in excess of the Prime Rate in effect from time to time, or, if less, the maximum rate permitted by law. Interest shall be calculated on the basis of a 360-day year for the actual number of days elapsed.
- (e) Accrued interest shall be due and payable (i) in respect of each Advance, quarterly in arrears on the last Business Day of each calendar quarter, and (ii) upon any payment of principal, on the amount paid.
  - (f) Borrower agrees to pay to Lender commitment fees as follows:

[\*\*\*]

- (g) The outstanding principal amount of an Advance or any accrued interest amounts thereon or any commitment fees that are not paid when due shall accrue interest on a daily basis at the lesser of (i) [\*\*\*] in excess of the Base Rate, or (ii) the maximum rate permitted by law, such accrual beginning on the date payment is due and continuing until the date payment is made in full.
- (h) All payments of principal, interest and fees described above shall be made to Lender in lawful money of the United States of America in immediately available funds.

#### ARTICLE III Conditions Precedent

- 3.01 Initial Conditions Precedent to Lender's Obligations. The obligation of Lender to perform its obligations under this Agreement is subject to the conditions precedent that Lender shall have received from Borrower each of the following documents on the date of this Agreement:
  - (a) The Note duly executed by Borrower;
- (b) The Security Agreement in the form acceptable to the parties (the "Security Agreement"), and the related financing statement in the form acceptable to the parties, in each case duly executed by Borrower;

- (c) Copies of (i) resolutions of the Board of Directors of Borrower approving this Agreement, the Note, and the Security Agreement and any other documents required or necessary to consummate the transactions contemplated in this Loan Agreement (collectively, the "Loan Documents"), the Purchase Agreement, the Investment and Royalty Agreement, and the Commercialization Agreement (together with the Loan Documents, collectively, the "Transaction Documents"), (ii) the Certificate of Incorporation of Borrower, and (iii) the Bylaws of Borrower, in each case certified by an appropriate officer of Borrower:
- (d) A certificate of the appropriate officers of Borrower certifying (i) the names and true signatures of the officers of Borrower authorized to sign the Transaction Documents, (ii) that the representations and warranties contained in Article IV of the Purchase Agreement are true and correct as of the date hereof, (iii) that Borrower has performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with on or prior to the date of this Agreement, and (iv) that no event has occurred and is continuing, which constitutes an Event of Default (as defined in Section 6.01 hereof) or would constitute an Event of Default but for the requirement that notice be given or time elapse or both;
- (e) A certificate of good standing (or comparable document) regarding Borrower from the State of Delaware; and
- (f) A legal opinion of Dickstein Shapiro Morin & Oshinsky, LLP, counsel for Borrower, regarding the Transaction Documents and the transactions contemplated thereby in the form acceptable to the parties.
- 3.02 Conditions Precedent to All Advances. The obligation of Lender to make each Advance shall be subject to the further conditions precedent that, on the date of such Advance:
- (a) The representations and warranties contained in Article IV of the Purchase Agreement (other than Sections 4.01 and 4.02) are true and correct in all material respects on and as of the date of such Advance, before and after giving effect to such Advance, as though made on and as of such date;
- (b) Borrower shall have performed, satisfied and complied with in all material respects all covenants, agreements and conditions required under the Transaction Documents to be performed, satisfied or complied with on or prior to the date of such Advance;
- (c) No event has occurred and is continuing, or would result from such Advance, which constitutes an Event of Default, or would constitute an Event of Default but for the requirement that notice be given or time elapse or both;
- (d) All principal amount of Advances, accrued interest or commitment fees under this Agreement, which are due and payable at the time of such Advance, shall have been paid in full; and

(e) If the Commitment shall have been increased pursuant to Section 2.01(d), Lender shall have received a new promissory note duly executed by Borrower in the form of the Note, except that the amount thereof shall be equal to the amount of the Commitment as so increased, to replace the Note executed by Borrower on the date hereof. Simultaneously with such replacement, the Note executed by the Borrower on the date hereof shall be cancelled and returned to Borrower and deemed null and void and of no further force and effect.

## ARTICLE IV REPRESENTATIONS AND WARRANTIES

4.01 Representations and Warranties. The representations and warranties of Borrower set forth in Article IV of the Purchase Agreement (excluding Sections 4.02, 4.14 through 4.18, 4.20, and 4.21 and after modifying Section 4.04 so that "Transaction Documents" shall mean this Agreement) are hereby incorporated by reference into this Agreement, and Borrower hereby makes such representations and warranties to Lender.

# ARTICLE V Covenants of Borrower

So long as any or all of the Advances or other obligations of Borrower under this Agreement shall remain unpaid or Lender shall have any Commitment hereunder, Borrower shall comply with the following covenants:

- 5.01 Compliance with Laws. Borrower shall comply, and cause each of its subsidiaries to comply, in all material respects with all applicable laws, rules, regulations and orders, in respect of the conduct of its business and the ownership of its properties, including without limitation with respect to the FFDCA, environmental issues, and taxes and other governmental changes, where the failure to so comply would have a material adverse effect on Borrower.
- 5.02 Transfers of Assets. Borrower shall not sell, convey, transfer, lease, license, assign or otherwise dispose of (whether in one transaction or in a series of transactions) (a) all or substantially all of its assets or properties (whether now owned or hereafter acquired) to any entity or person, or (b) any of its assets or properties except in the ordinary course of business, or in each case permit any of its subsidiaries to do so, if, in the case of this subsection (b), such sale, conveyance, transfer, lease, license, assignment or other disposition is likely to have a material adverse effect on Borrower or on Lender's rights hereunder.
- 5.03 Debt. Borrower shall not create or incur or allow to be created, incurred or exist, or permit any of its subsidiaries to create or incur or allow to be created, incurred or exist, any Debt, except (a) accounts payable incurred or created in the ordinary course of Borrower's business, (b) Debt incurred or created in the ordinary course of Borrower's business and which does not exceed [\*\*\*] in the aggregate, (c) Debt incurred or created solely for the purpose of

financing the acquisition of property (other than real property) and equipment for use in Borrower's business and which does not exceed [\*\*\*] in the aggregate, and (d) Debt which is junior and subordinate in right of payment to Borrower's obligations to Lender under the Loan Documents ("Junior Debt") so long as, prior to the creation of such Junior Debt, Lender has consented in writing to such Junior Debt (such consent not to be unreasonably withheld), and Lender and the holder of such Junior Debt have entered into a subordination agreement in form and substance reasonably satisfactory to Lender providing for the subordination of the Junior Debt to the obligations of Borrower under the Loan Documents.

- 5.04 Liens, Etc. Borrower shall not create or incur or allow to be created, incurred or exist, or permit any of its subsidiaries to create or incur or allow to be created, incurred or exist, any Lien upon or with respect to any of Borrower's or its subsidiaries' assets or properties, except (a) Permitted Liens, as defined in the Security Agreement, (b) purchase money Liens upon property and equipment of Borrower acquired for use in Borrower's business, securing the purchase price thereof or securing Debt incurred solely for the purpose of financing the acquisition thereof, and all of which Liens in the aggregate do not secure Debt in excess of [\*\*\*], (c) Liens securing capital lease obligations under which the Lessor's recourse is limited to the leased property, and (d) Liens securing indebtedness which is junior and subordinate in right of payment to Borrower's obligations to Lender under the Loan Documents ("Junior Liens") so long as, prior to the creation of such Junior Liens, Lender has consented in writing to such Junior Liens (such consent not to be unreasonably withheld), and Lender and the holder of such Junior Liens have entered into a subordination agreement in form and substance reasonably satisfactory to Lender providing for the subordination of the indebtedness secured by the Junior Liens to the obligations of Borrower under the Loan Documents.
- 5.05 Corporate Existence; Business. Borrower will (i) maintain and preserve in full force and effect its corporate existence, and (ii) continue to engage in the business in which it is engaged on the date hereof.
- 5.06 Exchange Act Registration. Borrower will cause its Common Stock to continue to be registered under Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), will comply in all material respects with its reporting and filing obligations under the Exchange Act, and will not take any action or file any documents to terminate or suspend such registration or terminate or suspend its reporting or filing obligations under the Exchange Act.
- 5.07 SEC Information. Upon request, Borrower will provide to Lender a copy of any publicly available forms, reports or other documents filed with the Securities and Exchange Commission.

- 5.08 Notice of Certain Events. Promptly, and in any event within five (5) Business Days after an executive officer of the company obtains knowledge thereof, Borrower will notify Lender of (a) the occurrence of an Event of Default, (b) any litigation, governmental proceeding or investigation or other event that is likely to materially and adversely affect the financial condition, properties, business, or results of operations of Borrower, or (c) any Change of Control.
- 5.09 Compliance with Certain Agreements. Borrower shall perform and fulfill all of its obligations under the License Agreement and the Research Agreement as necessary to maintain Borrower's rights in such agreements in full force and effect in all material respects. Borrower shall provide written notice to Lender within five (5) Business Days of Borrower's receipt of any notice from any other parties to the License Agreement or the Research Agreement proposing or threatening to terminate any such agreement.

#### ARTICLE VI Events of Default

6.01 Events of Default. The occurrence of each of the following events shall be considered an event of default ("Event of Default"):

- (a) Borrower shall fail to pay any principal of, or interest on, the Note when the same becomes due and payable and four (4) Business Days have elapsed following receipt of notice of such non-payment from Lender to Borrower;
- (b) Any representation or warranty made by Borrower under this Agreement shall prove to have been incorrect or untrue in any material respect when made or deemed made and such incorrect or untrue representation or warranty has a material adverse effect on Borrower or significantly impairs the prospect that Lender will be repaid in accordance with the terms of this Agreement and is not cured within thirty (30) days upon receipt of notice thereof by Borrower;
- (c) Borrower shall fail to perform or observe any term, covenant or agreement contained in this Agreement required to be performed or observed by Borrower (other than Section 5.02, 5.03 or 5.04) and such failure to perform or observe such term, covenant or agreement has a material adverse effect on Borrower or significantly impairs the prospect that Lender will be repaid in accordance with the terms of this Agreement and is not cured within thirty (30) days after receipt of notice thereof by Borrower;
- (d) Borrower shall fail to perform or observe the provisions of Section 5.02, 5.03 or 5.04 above, except, in the case of Section 5.04, if such Event of Default is based on a tax lien, judgment lien or materialman's lien, such judgment shall continue without discharge or stay for a period of sixty (60) days;
- (e) One or more judgments, decrees or orders for the payment of money shall be entered against Borrower or any of its subsidiaries involving in the aggregate a liability of

[\*\*\*] or more, and any such judgment, decree or order shall continue without discharge or stay for a period of sixty (60) days;

- (f) Borrower shall (i) commence a voluntary case under the federal bankruptcy laws (as now or hereafter in effect), (ii) file a petition seeking to take advantage of any other laws relating to bankruptcy, insolvency, reorganization, winding up or composition for adjustment of debts, (iii) consent to or fail to contest in a timely manner any petition filed against it in an involuntary case under such bankruptcy laws or other laws, (iv) apply for or consent to, or fail to contest in a timely and appropriate manner, the appointment of, or the taking of possession by, a receiver, custodian, trustee, or liquidator of itself or of a substantial part of its property, (v) admit in writing its inability to pay its debts as they become due, (vi) make a general assignment for the benefit of creditors, or (vii) take any corporate action for the purpose of authorizing or effecting any of the foregoing;
- (g) A case or other proceeding shall be commenced against Borrower or any of its subsidiaries in any court of competent jurisdiction seeking (i) relief under the federal bankruptcy laws (as now or hereafter in effect) or under any other laws relating to bankruptcy, insolvency, reorganization, winding up or adjustment of debts, or (ii) the appointment of a trustee, receiver, custodian, liquidator or the like for Borrower or any of its subsidiaries or for all or any substantial part of their respective assets, and such case or proceeding shall continue without dismissal or stay for a period of sixty (60) consecutive days, or an order granting the relief requested in such case or proceeding (including, but not limited to, an order for relief under such federal bankruptcy laws) shall be entered;
- (h) A Change of Control shall occur; provided, however, that a Change of Control, as defined in clauses (ii) and (iii) of the definition of Change of Control, shall not be an Event of Default so long as the surviving, acquiring or continuing entity has a net worth (after giving effect to the consummation of the applicable transaction and determined in accordance with generally accepted accounting principles) at least equal to the net worth of Borrower immediately prior to the consummation of the applicable transaction and such entity agrees in an enforceable written instrument to be bound by all the terms and conditions of this Agreement as if it were Borrower and a party hereto, which instrument shall be delivered a reasonably practicable time prior to the consummation of such transaction;
- (i) Borrower or any of its subsidiaries shall default in the performance or observance of any agreement or instrument relating to any Debt, or any other event shall occur or condition exist, and the effect of such default, event or condition is to cause or permit the holder of any such Debt to cause any such Debt to become due prior to its stated maturity;
- (j) the Borrower shall fail to perform or observe any term, covenant or agreement under the Security Agreement in any material respect;

- (k) There shall have been a material adverse change (other than with respect to matters relating to general economic conditions on Borrower's industry as a whole) in the financial condition, properties, business or results and operations of Borrower, taken as a whole, which materially adversely effects Borrower's ability to satisfy its obligations under the Loan Documents; provided, however, that in no event shall a material adverse change be deemed to have occurred by virtue of the incurrence by the Company or its Affiliates of any debt or other obligations permitted by this Agreement or the other Transaction Documents;
- (1) Borrower shall fail to meet the continued listing criteria of the Nasdaq SmallCap Market at any time if such failure shall continue for thirty (30) consecutive days following receipt of notice thereof by Borrower of the occurrence thereof from the Nasdaq SmallCap market or Lender;
- $\mbox{(m)}$  The License Agreement or the Research Agreement shall have been terminated;
  - (n) The Commercialization Agreement shall have been terminated; or
- (o) The Investment and Commission Agreement shall have been terminated.
- 6.02 Effect of Event of Default. If any Event of Default shall occur and be continuing, then Lender (i) may, by notice to Borrower, declare the Commitment and its obligation to make Advances to be terminated, whereupon the same shall forthwith terminate, (ii) may, by notice to Borrower, declare the Note, all interest thereon and all other amounts payable under this Agreement to be forthwith due and payable, whereupon the Note, all such interest and all such amounts shall become and be forthwith due and payable, without presentment, demand, protest or further notice of any kind, all of which are hereby expressly waived by Borrower, and (iii) exercise any rights or remedies under the Security Agreement; provided, however, that if an Event of Default specified in Section 6.01(f) or (g) shall occur, (A) the Commitment and the obligation of Lender to make Advances shall automatically be terminated and (B) the Note, all such interest and all such amounts shall automatically become and be due and payable, without presentment, demand, protest or any notice of any kind, all of which are hereby expressly waived by Borrower.

#### ARTICLE VII MISCELLANEOUS

- 7.01 Amendments. No amendment or waiver of any provision of this Agreement or the Note, nor consent to any departure by Borrower therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower and Lender, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.
- 7.02 Notices. All notices and other communications provided for hereunder shall be in writing, shall specifically refer to this Agreement, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder, and shall be deemed to have been sufficiently given for all purposes if (i) mailed by first class

certified or registered mail, postage prepaid, (ii) sent by nationally recognized overnight courier for next Business Day delivery, (iii) personally delivered, or (iv) made by telecopy or facsimile transmission with confirmed receipt.

If to Borrower: Discovery Laboratories, Inc.

350 South Main Street

Suite 307

Doyelstown, PA 18901-4874

Attn: President

Facsimile: (215) 340-3940

with a copy to: Roberts, Sheridan & Kotel
The New York Practice of

Dickstein Shapiro's Corporate & Finance Group

1177 Avenue of the Americas New York, NY 10036-2714 Attn: Ira L. Kotel

Facsimile: (212) 997-9880

If to Lender: PharmaBio Development Inc.

4709 Creekstone Drive

Riverbirch Bldg., Suite 200

Durham, NC 27703 Attn: President

Facsimile: (919) 998-2090

with a copy to: Smith, Anderson, Blount, Dorsett,

Mitchell & Jernigan, L.L.P. 2500 First Union Capitol Center

Raleigh, NC 27601

Attn: Christopher B. Capel Facsimile: (919) 821-6800

7.03 No Waiver; Remedies. No failure on the part of Lender to exercise, and no delay in exercising, any right hereunder or under the Notes shall operate as a waiver thereof; nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.

7.04 Right of Set-off. If an Event of Default shall have occurred and be continuing, Lender is hereby authorized at any time and from time to time, to the fullest extent permitted by law, to set off and apply any payment obligation by Lender to Borrower under the Transaction Documents against any and all of the obligations of Borrower now or hereafter existing under this Agreement and the Note, whether or not Lender shall have made any demand under this Agreement or the Note and although such obligations may be unmatured. Lender agrees promptly to notify Borrower after any such set-off and application, provided that the failure to give such notice shall not affect the validity of such set-off and application. The rights of Lender

under this Section 7.04 are in addition to other rights and remedies (including, without limitation, other rights of set-off) which Lender may have.

- 7.05 Attorneys' Fees. In the event that any dispute among the parties to the Loan Documents should result in litigation, the prevailing party in such dispute shall be entitled to recover from the losing party all fees, costs and expenses enforcing any right of such prevailing party under or with respect to the Loan Documents, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all fees, costs and expense of appeals.
- 7.06 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of Borrower and Lender and their respective successors and assigns, provided that neither Borrower nor Lender may assign or transfer any or all of its rights or obligations under the Loan Documents without the prior written consent of the other party and any attempted assignment without consent shall be null and void; provided, however, that Lender may at any time assign or transfer any of its rights or obligations under the Loan Documents to an Affiliate of Lender so long as such Affiliate agrees in an enforceable written instrument to be bound by all the terms and conditions of the Loan Documents as if it were Lender and a party thereto, which instrument shall be delivered a reasonably practicable time prior to such assignment.
- 7.07 Severability. To the extent any provision of this Agreement is prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.
- 7.08 Entire Agreement. This Agreement and the other Transaction Agreements embody the entire agreement and understanding between the parties hereto with respect to the subject matter thereof and supersede all prior oral or written agreements and understandings relating to the subject matter thereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in the Transaction Agreements shall affect, or be used to interpret, change or restrict, the express terms and provisions of the Agreements. If any provision contained in this Agreement shall be deemed to conflict with any provision of any of the other Transaction Agreements, then the provision contained in this Agreement shall be controlling.
- 7.09 Further Action. Each party shall, without further consideration, take such further action and execute and deliver such further documents as may be reasonably requested by the other party in order to carry out the provisions and purposes of this Agreement.
- 7.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which, when taken together, shall constitute one and the same instrument. This Agreement may be executed and delivered by telecopy or facsimile transmission and any execution by such means shall be deemed an original.
- 7.11 Publicity. Except as otherwise required by applicable law or by obligations pursuant to any listing agreement with or rules of any securities exchange or automated quotation

system, each party shall, and shall cause its respective Affiliates to, not, issue any press release or make any other public statement relating to, connected with or arising out of this Agreement or the matters contained herein without the other parties' prior written approval of the contents and the manner of presentation and publication thereof (which approval shall not be unreasonably withheld or delayed).

- 7.12 Termination by Borrower. At such time that all Advances and accrued interest have irrevocably been paid in full, the Commitment has expired or been terminated and Borrower has satisfied all of its obligations under this Agreement, Lender shall, at the request of Borrower, promptly, and in no event later than ten (10) Business Days thereafter, make, execute, endorse, acknowledge, file and/or deliver to Borrower any and all agreements, certificates, instruments or other documents, and take all other action, as reasonably requested by Borrower to terminate this Agreement.
- 7.13 Disclaimer. Neither Lender nor Borrower, nor any of such party's Affiliates, directors, officers, employees, subcontractors or agents shall have, under any legal theory (including, but not limited to, contract, negligence and tort liability), any liability to any other party hereto for any loss of opportunity or goodwill, or any type of special, incidental, indirect or consequential damage or loss, in connection with or arising out of this Agreement.
- 7.14 Governing Law. This Agreement, including, without limitation, the interpretation, performance, enforcement, breach or termination thereof and any remedies relating thereto, shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, as applied to agreements executed and performed entirely in the State of Delaware, without regard to conflicts of law rules.
- 7.15 Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the JCC (as defined in the Commercialization Agreement), which will use its good faith efforts to resolve the Dispute within ten (10) days. If the JCC is unable to resolve the Dispute in such period, the JCC will refer the Dispute to the Chief Executive Officers of Borrower and Lender. For all Disputes referred to the Chief Executive Officers, the Chief Executive Officers shall use their good faith efforts to meet at least two times in person and to resolve the Dispute within ten (10) days after such referral.
- 7.16 Arbitration. (a) If the parties are unable to resolve any Dispute under Section 7.15, then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 7.15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

- (b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by Borrower, one by Lender, and the third by the two so chosen. If both or either of Borrower or Lender fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this agreement, and any such party need not comply with the procedural provisions of this Section 7.16 in order to assert such counterclaim(s).
- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in Wilmington, Delaware or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60) day period. In addition, the following rules and procedures shall apply to the arbitration:
- (i) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 7.16.
- (ii) The decision of the arbitrators, which shall be in writing and state the findings the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.
- (iii) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.
- (iv) The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 7.16, and the costs of the arbitrator(s) shall be equally divided between the parties; provided, however, that each party shall bear the costs incurred in connection with any Dispute brought by such party that the arbitrators determine to have been brought in bad faith.

(e) Except as provided in the last sentence of Section 7.16(a), the provisions of this Section 7.16 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising with regard to this Agreement. Any party commencing a lawsuit in violation of this Section 7.16 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

[REST OF PAGE INTENTIONALLY LEFT BLANK; SIGNATURES ON FOLLOWING PAGE]

### [Signature Page to Loan Agreement]

IN WITNESS WHEREOF, the parties hereto have caused this Loan Agreement to be executed by their respective officers thereunto duly authorized, as of the date first above written.

BORROWER:

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

Name: David L. Lopez

Title: Vice President and General Counsel

LENDER:

PHARMABIO DEVELOPMENT INC.

By: /s/ Thomas C. Perkins

Name: Thomas C. Perkins

Title: Vice President and General Counsel

## EXHIBIT A DEFINITIONS

"Affiliate" shall mean, as to any person or entity, any corporation or business entity controlled by, controlling or under common control with such party or entity. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or income interest in such corporation or other business entity.

"Business Day" shall mean any day other than a Saturday, Sunday or legal holiday on which banks in North Carolina and New York are open for the conduct of their banking business.

"Change of Control" shall mean the occurrence of any of the following events: (i) the acquisition, whether directly or indirectly, by any person or entity, including a "group" as defined in Section 13(d)(3) of the Exchange Act, of fifty percent (50%) or more of the Common Stock of Borrower; (ii) Borrower shall merge or consolidate (or engage in any other share exchange, acquisition or business combination transaction) with or into another corporation or other entity, with the effect that the persons who were the shareholders of Borrower immediately prior to the effective time of such transaction hold less than fifty-one percent (51%) of the combined voting power of the outstanding equity securities of the surviving, continuing or acquiring entity in such transaction; (iii) Borrower shall sell, convey, transfer, lease, license, assign or otherwise transfer or dispose of (whether in one transaction or a series of transactions) all or substantially all of its assets or properties (whether now owned or hereafter acquired) to any person or entity, or permit any of its subsidiaries to do so; or (iv) at any time during any calendar year, fifty percent (50%) or more of the members of the full Board of Directors of Borrower shall have resigned or been removed or replaced. The determination of "combined voting power" shall be based on the aggregate number of votes that are attributable to outstanding securities entitled to vote in the election of directors, general partners, managers or persons performing analogous functions to directors of the entity in question, without regard to contractual arrangements or rights accruing in special circumstances.

"Debt" shall mean (i) indebtedness for borrowed money, (ii) obligations evidenced by bonds, debentures, notes or other similar instruments, (iii) obligations to pay the deferred purchase price of property or services, (iv) obligations as lessee under leases which shall have been or should be, in accordance with generally accepted accounting principles, recorded as capital leases, and (v) obligations under direct or indirect guaranties in respect of, and obligations (contingent or otherwise) to purchase or otherwise acquire, or otherwise to assure a creditor against loss in respect of, indebtedness or obligations of others of the kinds referred to in clauses (i) through (iv) above; provided, however, Debt shall not include any Debt of Borrower under this Agreement.

"FDA" shall mean the United States Food and Drug Administration.

"FFDCA" shall mean the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and all regulations promulgated thereunder.

"License Agreement" shall mean the Sublicense Agreement dated October 28, 1996 between Johnson & Johnson and Ortho Pharmaceutical Corporation, as licensors, and the Company (formerly known as Acute Therapeutics, Inc.), as licensee.

"Liens" shall mean any lien, security interest, mortgage, pledge, encumbrance, charge or claim.

"NDA" shall mean a "new drug application" as such term is used under the  $\ensuremath{\mathsf{FFDCA}}$ .

"Prime Rate" shall mean the rate which First Union National Bank (or its successor) announces from time to time as its prime lending rate, the Prime Rate to change when and as such prime lending rate changes.

"Product" shall have the meaning given such term under the Investment and Commission Agreement.

"Research Agreement" shall mean the Research Funding and Option Agreement dated March 1, 2000 between the Scripps Research Institute and the Company.

#### PROMISSORY NOTE

\$8,500,000 December \_\_, 2001

FOR VALUE RECEIVED, DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), hereby promises to pay to the order of PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender"), in lawful money of the United States of America in immediately available funds, the lesser of (i) the principal sum of Eight Million, Five Hundred Thousand Dollars (\$8,500,000) and (ii) the aggregate unpaid principal amount of all Advances (as defined in the Loan Agreement referred to below) made by Lender to Borrower pursuant to the Loan Agreement (as defined below), together with interest accrued thereon. The interest shall accrue on the unpaid principal amount of each Advance at the rates and in the manner provided in the Loan Agreement. Payment of the principal amount of this Note and accrued interest on this Note shall be made at the times and in the manner provided in the Loan Agreement. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Loan Agreement.

Each Advance made by Lender to Borrower, and all payments made on account of the principal amount hereof, shall be recorded and endorsed by Lender on the grid attached hereto which is a part of this Note. Failure to so record and endorse such Advances and payments, however, shall not affect Borrower's obligations in respect of such Advances.

This Promissory Note is the Note referenced in the Loan Agreement between Borrower and Lender dated as of the date of this Note (as same may be amended from time to time, the "Loan Agreement"), and is entitled to the benefits of the Loan Agreement. The Loan Agreement, among other things, (i) provides for the making of certain Advances by Lender to Borrower from time to time, the principal amount of each such Advance being a principal amount evidenced by this Note, and (ii) provides that this Note is secured by, and Borrower has granted a security interest in, certain of its assets as set forth in that certain Security Agreement between Borrower and Lender dated as of the same date as this Note.

In case an Event of Default shall occur and be continuing and not cured prior to the expiration of any applicable cure or grace periods set forth in the Loan Agreement, the unpaid principal amount of, and accrued interest on, this Note may be declared to be due and payable in the manner and with the effect provided in the Loan Agreement.

Borrower hereby waives presentment, demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance and enforcement of this Note.

This Note is subject to early termination as set forth in the Loan Agreement. This Note may be voluntarily prepaid, in whole or in part, on the terms and conditions set forth in the Loan Agreement. Provided that no Advances or accrued interest are outstanding and have irrevocably been paid in full and the Commitment shall have expired or been terminated in accordance with the terms of the Loan Agreement, the Lender shall, at the request of Borrower, promptly, and in no event later than ten (10) Business Days after notice from Borrower, cancel and return this Note to Borrower.

This Note shall be governed by and construed in accordance with the law of the State of Delaware without regard to the conflicts of law rules of such state.

This Note may not be assigned by Lender except to an Affiliate of Lender which agrees in an enforceable written instrument to be bound by all the terms and conditions of this Note as if it were Lender, which instrument shall be delivered a reasonably practicable time prior to such assignment.

Lender and Borrower agree that disputes relating to this Note shall be subject to the provisions of the Loan Agreement entitled "Internal Review" and "Arbitration" set forth in Sections 7.15 and 7.16 thereof, respectively.

BORROWER:

DISCOVERY LA	BORATORIES,	INC.
--------------	-------------	------

By:	
Name:	
Title:	

# ADVANCES AND PAYMENTS OF PRINCIPAL

#### SECURITY AGREEMENT

THIS SECURITY AGREEMENT (this "Agreement") is dated and entered into as of December 10, 2001, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender").

#### WITNESSETH:

WHEREAS, Borrower and Lender are parties to a Loan Agreement (as amended, modified or supplemented from time to time, the "Loan Agreement") dated as of the same date hereof, pursuant to which, among other things, Borrower is delivering to Lender the Note (as defined in the Loan Agreement); and

WHEREAS, it is a condition precedent to the performance of Lender under the Loan Agreement that Borrower enter into this Agreement;

NOW, THEREFORE, in consideration of the benefits to Borrower, the receipt and legal sufficiency of which are hereby acknowledged, Borrower hereby makes the following representations and warranties to Lender and hereby covenants and agrees with Lender as follows:

1. Definitions. The following terms, as used in this Agreement, shall have the following meanings:

"Collateral" shall mean (but only to the extent the following elements of the Collateral relate to or arise out of or in connection with the sale, lease, license, conveyance, transfer or disposition of any right, title or interest in, to or under the Product, the Product Intellectual Property, or the Product Agreements in the Territory) all right, title and interest of Borrower in, to and under any and all of the following, whether now existing or hereafter existing or acquired from time to time, in the Territory: (a) all Accounts, Chattel Paper, Contract Rights, Contracts, Commercial Tort Claims, Deposit Accounts, Documents, General Intangibles, Instruments, monies, Payment Intangibles, Promissory Notes and Receivables, relating to, arising out of or in connection with any sale, lease, license, conveyance, transfer or disposition of any right, title or interest in, to or under the Product, the Product Intellectual Property, or the Product Agreements; (b) all regulatory applications, filings or similar items related to the Product, including without limitation the NDA for the Product and all supplements, records, and reports that are required to be maintained under applicable FDA regulations and all related correspondence to and from the FDA, and all clinical data related to any such regulatory applications, filings or similar items; (c) all books, records, computer information, files, documents, data or other materials related to or arising out of or in connection with any and all of the foregoing; and (d) all Proceeds of any and all of the foregoing; provided, however, that the Collateral shall not include the Product Intellectual Property or Product Agreements themselves; provided, further, that the Collateral

shall not include Proceeds derived from or in connection with the sale, lease, license, conveyance, transfer or disposition of any right, title or interest in Intellectual Property of the Borrower to the extent, and only to the extent, that such Proceeds relate to the sale, lease, license, conveyance, transfer or disposition of any right, title or interest in products other than the Product.

"Contracts" shall mean all contracts, agreements and licenses between Borrower and one or more other parties, or under or with respect to which Borrower has rights.

"Contract Rights" shall mean all rights of Borrower (including, without limitation, all rights to payment) under each Contract.

"FDA" shall mean the United States Food and Drug Administration.

"Intellectual Property" shall mean all: trade, business and product names; trademarks; service marks; copyrights; patents; discoveries; trade secrets; business and technical information; proprietary compilations of data or information; know-how; inventions; formulas and techniques; methods; regulatory filings; computer software; all intellectual property rights, registrations, licenses and applications pertaining to any of the foregoing; and all related documentation and goodwill.

"License Agreement" shall mean the Sublicense Agreement dated October 28, 1996 between Johnson & Johnson and Ortho Pharmaceutical Corporation, as licensors, and the Company (formerly known as Acute Therapeutics, Inc.), as licensee (including any amendment, restatement, replacement, etc. thereof).

"Liens" shall mean any lien, security interest, mortgage, pledge or encumbrance.

"NDA" shall mean a "new drug application" as such term is used under the United States Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder.

"Obligations" shall mean all indebtedness, obligations and liabilities of Borrower to Lender arising under or in connection with the Note (as defined in the Loan Agreement) and under or in connection with each of the Loan Agreement and this Agreement.

"Permitted Liens" shall mean any of the following: (a) liens for taxes, assessments or other governmental charges incurred in the ordinary course of business and for which no interest, late charge or penalty is attaching or which are being contested in good faith by appropriate proceedings; (b) liens, not delinquent, created by statute in connection with worker's compensation, unemployment insurance, social security and similar statutory obligations; and (c) liens of mechanics, materialmen, carriers, warehousemen or other like statutory or common law liens securing obligations incurred in good faith in the ordinary course of business that are not due and payable.

"Product" shall mean the product currently known as Surfaxin, as such name may change from time to time, for any and all formulations and delivery mechanisms for the indications of

idiopathic respiratory distress syndrome ("IRDS"), meconium aspiration syndrome ("MAS"), and acute respiratory distress syndrome ("ARDS"); provided, however, that upon the occurrence of the First Milestone (as defined in the Investment and Commission Agreement referred to in the Loan Agreement), the Product shall not include the indication of ARDS.

"Product Intellectual Property" shall mean all Intellectual Property which is embodied, used or included in, or which otherwise comprises or constitutes the Product.

"Product Agreements" shall mean the License Agreement and the Research Agreement.

"Receivable" shall mean any "account" as such term is defined in the Uniform Commercial Code as in effect on the date hereof and as in effect from time to time in the State of Delaware, and, in any event, shall include, but shall not be limited to, all of Borrower's rights to payment for goods sold, leased or licensed or services performed by Borrower, whether now in existence or arising from time to time hereafter, including, without limitation, rights evidenced by an account, note, contract, security agreement, chattel paper or other evidence of indebtedness or security, together with (a) all security pledged, assigned, hypothecated or granted to or held by Borrower to secure the foregoing, (b) all of Borrower's right, title and interest in and to any goods, the sale of which gave rise thereto, (c) all guarantees, endorsements and indemnifications on, or of, any of the foregoing, (d) all powers of attorney for the execution of any evidence of indebtedness or security or other writing in connection therewith, (e) all books, records, ledger cards, and invoices relating thereto, (f) all evidences of the filing of financing statements and other statements and the registration of other instruments in connection therewith and amendments thereto, notices to other creditors or secured parties, and certificates from filing or other registration officers, (g) all credit information, reports and memoranda relating thereto and (h) all other writings related in any way to the foregoing.

"Research Agreement" shall mean the Research Funding and Option Agreement dated March 1, 2000 between the Scripps Research Institute and the Company (including any amendment, restatement, replacement, etc. thereof).

"Territory" shall mean the United States (including Puerto Rico).

All capitalized terms not expressly defined herein are used as such terms are defined in the Uniform Commercial Code as in effect on the date hereof and as in effect from time to time in the State of Delaware.

- 2. Grant of Security Interests. As security for the prompt and complete payment and performance of all of the Obligations, Borrower does hereby assign, transfer, pledge, and hypothecate unto Lender, and does hereby grant to Lender, subject to Permitted Liens, a continuing security interest of first priority in, all of the right, title, and interest of Borrower in, to, and under the Collateral.
- 3. Representations and Warranties of Borrower. Borrower represents and warrants to Lender as follows:

- (a) The execution and delivery by Borrower of this Agreement and the financing statements described herein (collectively, the "Security Documents"), and the performance of the terms and obligations therein, are within Borrower's corporate powers and have been duly authorized by all necessary corporate action on the part of Borrower. The Security Documents have been duly executed and delivered by Borrower and constitute valid and legally binding obligations of Borrower enforceable against Borrower in accordance with their terms except as such enforceability may be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting the enforcement of creditors' rights generally and as to limitations on the enforcement of the remedy of specific performance and other equitable remedies.
- (b) Borrower is the owner of the Collateral and has good, valid and marketable title to the Collateral, free and clear of all Liens except for those in favor of Lender and Permitted Liens.
- (c) Except for the filing of financing statements with the State of Delaware and, only in the case of any patent and trademark matters, filings with the United States Patent and Trademark Office and, only in the case of any copyright matters, filings with the United States Copyright Office, necessary to perfect the security interests created hereunder, no authorization, approval, or other action by, and no notice to or filing with, any governmental authority or regulatory body is required either for the grant by Borrower of the security interest hereunder or for the execution, delivery, or performance of this Agreement by Borrower or for the perfection of such security interest or the exercise by Lender of its rights hereunder to the Collateral, except for those elements of Collateral that constitute monies or Deposit Accounts. Upon the execution of this Agreement and the completion of such filings in compliance with all applicable legal requirements, Lender will have a perfected, first priority security interest in the Collateral (other than those elements of Collateral that constitute monies or Deposit Accounts).
- (d) Neither the execution or delivery by Borrower of the Security Documents, nor the performance of their respective terms and obligations, will (i) violate Borrower's charter or bylaws, (ii) constitute a material breach or default under any agreement or instrument to which Borrower is a party or by which Borrower is bound; (iii) violate any applicable law, rule or regulation, or (iv) violate any order, writ, injunction, decree or judgment of any court or governmental authority applicable to or binding upon Borrower.
- 4. Transfer of Collateral and Other Liens. The provisions of Sections 5.02 and 5.04 of the Loan Agreement are hereby incorporated herein by reference.
- 5. Other Financing Statements. Borrower represents, warrants and covenants to and with Lender that: there exists no financing statement (or similar statement or instrument of registration under the law of any jurisdiction) covering or purporting to cover any security interest of any kind in the Collateral, and Borrower will not execute or authorize to be filed in any public office any financing statement (or similar statement or instrument of registration under the law of any jurisdiction) relating to the Collateral, as applicable, except financing statements (or similar statements or instruments of registration under the law of any jurisdiction)

filed or to be filed in respect of and covering the security interests granted to Lender by Borrower.

## 6. Further Assurances.

- (a) Borrower, upon reasonable request of Lender, will promptly deliver and execute or cause to be delivered and executed, in form and content satisfactory to Lender, any financing, continuation, termination, or security interest filing statements, security agreement, assignment, or other document or instrument as Lender may reasonably request in order to perfect, preserve, maintain, or continue the perfection of Lender's security interest in the Collateral, or its priority, including without limitation any document or instrument necessary to record Lender's security interest in any state or county of any state, the United States Patent and Trademark Office or the United States Copyright Office. Borrower will pay the reasonable costs of filing any financing, continuation, termination, or security interest filing statement, assignment or other document or instrument as well as any recordation or transfer tax required by law to be paid in connection with the filing or recording thereof.
- (b) Borrower will, at its own expense, make, execute, endorse, acknowledge, file and/or deliver to Lender from time to time such lists, descriptions and designations of its Collateral, documents of title, vouchers, invoices, schedules, confirmatory assignments, conveyances, financing statements, transfer endorsements, powers of attorney, certificates, reports and other assurances or instruments and take such further steps relating to the Collateral and other property or rights covered by the security interest hereby granted, as reasonably requested by Lender or which is necessary to perfect, preserve or protect its security interest in the Collateral.
- (c) Upon the occurrence of the First Milestone (as defined in the Investment and Commission Agreement referred to in the Loan Agreement), Lender shall, at the request of Borrower, promptly, and in no event later than ten (10) Business Days thereafter, make, execute, endorse, acknowledge, file and/or deliver to Borrower and all agreements, certificates, instruments or other documents, and take all other action, as reasonably requested by Borrower, to release the Collateral and terminate the security interests granted, pledged or secured hereunder to the extent that the Collateral or any security interest granted, pledged or secured hereunder arises out, under or in connection with solely the ARDS indication for the Product.
- (d) Upon the irrevocable payment in full of all Advances and accrued interest thereon and the termination or expiration of the Commitment, Lender shall, at the request of Borrower, promptly, and in no event later than ten (10) Business Days thereafter, make, execute, endorse, acknowledge, file and/or deliver to Borrower any and all agreements, certificates, instrument or other documents, and take all other action, as reasonably requested by Borrower, to release all of the Collateral and effectuate the termination of all of the security interests granted, pledged or secured hereunder.

## 7. Additional Agreements.

- (a) Insurance. Borrower shall maintain insurance on the Collateral with financially sound and reputable insurance companies and in such amounts as are customary in Borrower's industry, to the extent that it is customary in Borrower's industry to insure a particular item of Collateral.
- (b) Ownership and Maintenance of the Collateral. Borrower shall, subject to normal wear and tear, keep all tangible Collateral, if any, in good condition. Borrower shall defend the Collateral against all claims and demands of all persons at any time claiming any interest therein adverse to Lender.
- (c) Taxes. Borrower shall pay as and when due and payable all taxes, levies, license fees, assessments, and other impositions levied on the Collateral or any part thereof for its use and operations, except for all taxes, levies, license fees, assessments, and other impositions levied on the Collateral which are being contested by the Borrower in good faith.
- (d) Litigation and Proceedings. Borrower shall commence and diligently prosecute in its own name, as the real party in interest, for its own benefit, and at its own expense, such suits, administrative proceedings, or other actions for infringement or other damages as are necessary to protect the Collateral. Borrower shall provide to Lender any information with respect thereto reasonably requested by Lender.
- 8. Power of Attorney. Borrower hereby appoints Lender as Borrower's true and lawful attorney, with full power of substitution, to do any or all of the following, in the name, place, and stead of Borrower, as the case may be: (a) file this Agreement (or an abstract hereof) or any other document describing Lender's interest in the Collateral with any appropriate governmental office (including, without limitation, the State of Delaware or any political subdivision thereof and the United States Patent and Trademark Office or the United States Copyright Office); and (b) following an Event of Default that has occurred and is continuing and not cured prior to the expiration of any applicable cure or grace periods set forth in the Loan Agreement, (i) endorse Borrower's name on all applications, documents, papers, and instruments necessary for Lender to use or maintain the Collateral, as applicable; (ii) ask, demand, collect, sue for, recover, impound, receive, and give acquittance and receipts for money due or to become due under or in respect of any of the Collateral; (iii) file any claims or take any action or institute any proceedings that Lender may deem necessary or desirable for the collection of any of the Collateral, or otherwise enforce Lender's rights with respect to any of the Collateral; (iv) assign, pledge, convey, or otherwise transfer title in or dispose of the Collateral, to any person; and (v) take any action and execute any instrument that Lender may deem necessary or advisable to accomplish the purposes of this Agreement.
- 9. Right to Inspect. Subject to (i) all applicable legal requirements, including without limitation, those requirements of the FDA and (ii) the agreement of Lender, on its behalf and on behalf of its employees, to ensure that the Lender and its employees comply with all of the confidentiality obligations set forth in any confidentiality agreement between the parties, Borrower grants to Lender and its employees and agents the right to visit Borrower's plants,

corporate offices, and facilities to inspect the Collateral at reasonable times during regular business hours with prior written notice to Borrower.

10. Name of Borrower, Place of Business, and Location of Collateral. Borrower represents and warrants that its correct legal name is as specified on the signature lines of this Agreement, and each legal or trade name of Borrower for the previous seven (7) years (if different from Borrower's current legal name) is as specified below the signature lines of this Agreement. Without the prior written notice to Lender of at least forty-five (45) days, Borrower will not change its name, change its state of incorporation, dissolve, merge, or consolidate with any other person. Borrower represents and warrants that its state of incorporation is as specified in the preamble to this Agreement and that the address of its chief executive office is as specified below the signature lines of this Agreement. The Collateral and all books and records pertaining thereto will be located at Borrower's chief executive office specified below. Borrower may establish a new location for the Collateral or any part thereof, or the books and records concerning the Collateral or any part thereof, only if (a) it shall have given to Lender prior written notice of its intention so to do, clearly describing such new location and providing such other information in connection therewith as Lender may reasonably request, and (b) with respect to such new location, it shall have taken all action necessary to maintain the security interest of Lender in the Collateral intended to be granted hereby at all times fully perfected and in full force and effect.

## 11. Rights and Remedies upon Default.

- (a) Borrower agrees that, if any Event of Default (as defined in the Loan Agreement) shall have occurred and is continuing and not cured prior to the expiration of any applicable cure or grace periods set forth in the Loan Agreement, then and in every such case, Lender, in addition to any rights now or hereafter existing under applicable law, and upon written notice to Borrower, shall have all rights as a secured creditor under the Uniform Commercial Code in all relevant jurisdictions and may:
  - (i) personally, or by agents or attorneys, immediately take or retake possession of the Collateral or any part thereof;
  - (ii) instruct the obligor or obligors on any agreement, instrument or other obligation constituting the Collateral to make any payment required by the terms of such agreement, instrument or obligation directly to Lender;
  - (iii) sell, assign or otherwise liquidate, or direct Borrower to sell, assign or otherwise liquidate, any or all of the Collateral or any part thereof, and take possession of the proceeds of any such sale or liquidation; and
  - (iv) take possession of the Collateral or any part thereof by directing Borrower in writing to deliver the same to Lender at any place or places designated by Lender; it being understood that Borrower's obligation so to deliver the Collateral is of the essence of this Agreement and that, accordingly, upon

application to a court of equity having jurisdiction, Lender shall be entitled to a decree requiring specific performance by Lender of said obligation.

- (b) In the event that an Event of Default has occurred and is continuing and not cured prior to the expiration of any applicable cure or grace periods set forth in the Loan Agreement, Borrower shall pay on demand all costs and expenses, including, without limitation, reasonable attorneys' fees and expenses, incurred by or on behalf of Lender (i) in enforcing the Obligations, and (ii) in connection with the taking, holding, preparing for sale or other disposition, selling, managing, collecting, or otherwise disposing of the Collateral. All of such costs and expenses (collectively, the "Liquidation" Costs") together with interest thereon at the interest rate specified in the Note, from the date of payment until repaid in full, shall be paid by Borrower to Lender on demand and shall constitute and become a part of the Obligations secured hereby. Any proceeds of sale or other disposition of the Collateral will be applied by Lender to the payment of Liquidation Costs, and any balance of such proceeds will be applied by Lender to the payment of the remaining Obligations in such order and manner of application as Lender may determine. Borrower hereby grants to Lender, as security for the full and punctual payment and performance of the Obligations, a continuing security interest in and lien on all now or hereafter existing balances, credits, accounts, deposits, and all other sums credited by, maintained with, or due from Lender or any affiliate of Lender to Borrower; and regardless of the adequacy of any Collateral or other means of obtaining repayment of the Obligations, Lender may at any time and without notice to Borrower set off the whole or any portion or portions of any or all such balances, credits, accounts, deposits, and other sums against any and all of the Obligations.
- (c) If the sale or other disposition of the Collateral fails to satisfy in full the Obligations, Borrower shall remain liable to Lender for any deficiency.
- 12. Remedies Cumulative. Each right, power, and remedy of Lender as provided for in this Agreement or now or hereafter existing at law or in equity or by statute or otherwise shall be cumulative and concurrent and shall be in addition to every other right, power, or remedy provided for in this Agreement or now or hereafter existing at law or in equity or by statute or otherwise, and the exercise or beginning of the exercise by Lender of any one or more of such rights, powers, or remedies shall not preclude the simultaneous or later exercise by Lender of any or all such other rights, powers, or remedies.
- 13. Amendments, Etc. No amendment or waiver of any provision of this Agreement, nor consent to any departure by Borrower herefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower and Lender, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.
- 14. Notices. All notices and other communications provided for hereunder shall be in writing, shall specifically refer to this Agreement, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder and shall be deemed to have been sufficiently given for all purposes if (i) mailed by first class certified or registered mail, postage prepaid, (ii) sent by nationally recognized

overnight courier for next business day delivery, (iii) personally delivered, or (iv) made by telecopy or facsimile transmission with confirmed receipt.

## If to Lender:

PharmaBio Development Inc. 4709 Creekstone Drive Riverbirch Bldg., Suite 200 Durham, NC 27703

Attention: President Facsimile: (919) 998-2090

# with a copy to:

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P.

2500 First Union Capitol Center

Raleigh, NC 27601

Attention: Christopher B. Capel

Facsimile: (919) 821-6800

## If to Borrower:

Discovery Laboratories, Inc. 350 Main Street, Suite 307 Doylestown, PA 18901-4874

Attention: President and General Counsel

Facsimile: (215) 340-3940

## with a copy to:

Roberts Sheridan & Kotel
The New York Practice of Dickstein Shapiro's
Corporate & Finance Group
1177 Avenue of the Americas
New York, NY 10036-2714
Attention: Ira L. Kotel
Facsimile: (212) 835-1400

- 15. No Waiver; Remedies. No failure on the part of Lender to exercise, and no delay in exercising, any right hereunder or under the Loan Agreement or the Notes shall operate as a waiver thereof; nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.
- 16. Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of Borrower and Lender and their respective successors and assigns, provided that

neither Borrower nor Lender may assign or transfer any or all of its rights or obligations under the Security Documents without the prior written consent of the other party and any attempted assignment without consent shall be null and void; provided, however, that Lender may at any time assign or transfer any of its rights or obligations under the Security Documents to an Affiliate of Lender so long as such Affiliate agrees in an enforceable written instrument to be bound by all the terms and conditions of the Security Documents as if it were Lender and a party hereto, which instrument shall be delivered a reasonably practicable time prior to such an assignment.

- 17. Severability. To the extent any provision of this Agreement is prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.
- 18. Entire Agreement. This Agreement and the other Loan Documents and Security Documents embody the entire agreement and understanding between the parties hereto and supersede all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in the Loan Documents and Security Documents shall affect, or be used to interpret, change or restrict, the express terms and provisions of the Loan Documents and Security Documents.
- 19. Further Action. Each Party shall, without further consideration, take such further action and execute and deliver such further documents as may be reasonably requested by the other party to carry out the purposes and provisions of the Security Documents.
- 20. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which, when taken together, shall constitute one and the same instrument. This Agreement may be executed and delivered by telecopy or facsimile transmission and any execution by such means shall be deemed an original.
- 21. Governing Law. This Agreement, including, without limitation, the interpretation, performance, enforcement, breach or termination thereof and any remedies relating thereto, shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, as applied to agreements executed and performed entirely in the State of Delaware, without regard to conflicts of law rules.
- 22. Internal Review. In the event that a dispute, difference, claim, action, demand, request, investigation, controversy, threat, discovery request or request for testimony or information or other question arises pertaining to any matters which arise under, out of, in connection with, or in relation to this Agreement (a "Dispute") and either party so requests in writing, prior to the initiation of any formal legal action, the Dispute will be submitted to the JCC (as defined in the Commercialization Agreement), which will use its good faith efforts to resolve the Dispute within ten (10) days. If the JCC is unable to resolve the Dispute in such period, the JCC will refer the Dispute to the Chief Executive Officers of Borrower and Lender. For all Disputes referred to the Chief Executive Officers, the Chief Executive Officers shall use

their good faith efforts to meet at least two times in person and to resolve the Dispute within ten (10) days after such referral.

- 23. Arbitration. (a) If the parties are unable to resolve any Dispute under Section 22, then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand". Thereupon such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 23. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.
- (b) The arbitration panel will be composed of three arbitrators, one of whom will be chosen by Borrower, one by Lender, and the third by the two so chosen. If both or either of Borrower or Lender fails to choose an arbitrator or arbitrators within 14 days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within 14 days after their appointment, the American Arbitration Association shall, upon the request of both or either of the parties to the arbitration, appoint the arbitrator or arbitrators required to complete the panel. The arbitrators shall have reasonable experience in the matter under dispute. The decision of the arbitrators shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrators may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this agreement, and any such party need not comply with the procedural provisions of this Section 23 in order to assert such counterclaim(s).
- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in Wilmington, Delaware or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Commercial Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a sixty (60) day period. In addition, the following rules and procedures shall apply to the arbitration:
- (e) The arbitrators shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 23.
- (f) The decision of the arbitrators, which shall be in writing and state the findings the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder.

- (g) The arbitrators shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No party shall seek punitive damages in relation to any matter under, arising out of, or in connection with or relating to this Agreement in any other forum.
- (h) The parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 23, and the costs of the arbitrator(s) shall be equally divided between the parties; provided, however, that each party shall bear the costs incurred in connection with any Dispute brought by such party that the arbitrators determine to have been brought in bad faith.
- (i) Except as provided in the last sentence of Section 23(a), the provisions of this Section 23 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising with regard to this Agreement. Any party commencing a lawsuit in violation of this Section 23 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

[THE REMAINDER OF THE PAGE IS INTENTIONAL LEFT BLANK; SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective duly authorized officers, as of the date first above written.

BORROWER:

DISCOVERY LABORATORIES, INC.

By: /s/ David L. Lopez

Name: David L. Lopez

Title: Vice President and General Counsel

Legal or tradename of Borrower for the previous seven (7) years

- 1. Ansan Pharmaceuticals, Inc.
- 2. Ansan, Inc.

Address of chief executive office of Borrower

Discovery Laboratories, Inc. 350 Main Street, Suite 307 Doylestown, PA 18901-4874

LENDER:

PHARMABIO DEVELOPMENT INC.

By: /s/ Thomas C. Perkins

-----

Name: Thomas C. Perkins

Title: Vice President and General Counsel

# FOR IMMEDIATE RELEASE

#### Contact:

Quintiles Transnational Corp. Discovery Laboratories, Inc.

Tom Fuldner Deni M. Zodda, Ph.D

Media Relations Sr. Vice President, Business Development

919 998 2052 215 340 4699

tom.fuldner@quintiles.com dzodda@discoverylabs.com

Greg Connors BMC Communications Group

Investor Relations Brad Miles

919 998 2000 212 477 9007 ext. 17 Invest@quintiles.com brad@bmccommunications.com

# DISCOVERY LABORATORIES AND QUINTILES TO COMMERCIALIZE SURFAXIN(R)

Doylestown, PA and Research Triangle Park, N.C. - December 11, 2001- Discovery Laboratories, Inc. (Nasdaq: DSCO) and Quintiles Transnational Corp. (Nasdaq: QTRN) today announced a sales and marketing alliance to commercialize in the United States Discovery's Surfaxin(R) (lucinactant), a novel, humanized lung surfactant for the treatment of respiratory distress syndrome (RDS) in premature newborns and meconium aspiration syndrome (MAS) in full-term newborns. In addition, the alliance anticipates a collaboration on Surfaxin(R) for the treatment of adult respiratory distress syndrome (ARDS). Currently, Discovery is conducting three Phase III clinical trials for RDS and MAS as well as a Phase II clinical trial for ARDS.

The agreement calls for Quintiles, through its strategic investment group, PharmaBio Development, to purchase \$3 million of Discovery common equity at \$3.79 per share and to make available a line of credit of up to \$8.5 million to \$10 million to fund pre-marketing activities associated with the launch of Surfaxin(R) in the United States as Discovery achieves certain milestones. In addition, PharmaBio Development has agreed to fund the sales and marketing costs for Surfaxin(R) for seven years of Surfaxin(R) commercialization. PharmaBio Development may also make certain milestone payments which will be used to offset outstanding line of credit loans to Discovery. In return, PharmBio Development will receive a commission on net sales over a 10-year period.

Discovery has also provided PharmaBio Development with warrants covering approximately 350,000 shares of Discovery common stock at an exercise price of \$3.48 per share. In addition, for each million dollars made available under the line of credit, PharmaBio Development will receive warrants to purchase approximately 38,000 shares of Discovery's common stock at an exercise price of \$3.03 per share.

Innovex, Quintiles' commercialization unit, will hire, train and deploy a dedicated sales force to promote Surfaxin(R) in the United States. Quintiles also expects to deploy a wide range of commercialization services in pre- and post-launch periods to help drive product sales. The majority of the line of credit will be used to fund Quintiles' pre-marketing services, including a market verification study to be commenced by the Lewin Group, Quintiles' consultancy unit.

Discovery's Surfaxin(R) is the first humanized peptide-based synthetic surfactant that mimics protein B and is believed to be the only product in the world being developed for MAS. RDS in premature infants is a breathing disorder in which the lungs of infants do not stay open due to an insufficient amount of surfactant, which is produced naturally as lungs mature. Approximately 50,000 cases of RDS in premature infants occur in the United States annually. MAS results when a full-term baby inhales meconium, a material produced in the intestine of a full-term baby before birth. The aspirated meconium in the lungs produces inflammation, which degrades the natural lung surfactant. Severe respiratory distress is a result. Approximately 26,000 cases of MAS occur in the United States annually.

"We are extremely pleased to be partnered with Quintiles - its reputation for uniquely tailored commercialization agreements with leading emerging biopharmaceutical companies is what attracted us to them," said Robert J. Capetola, President and Chief Executive Officer of Discovery Laboratories. "Our agreement allows us to retain product ownership, have sales and marketing expertise in place for a maximum launch effort of Surfaxin(R) in late 2003-2004, and forgo creating costly infrastructure investment prior to product approval to potentially achieve margins common to specialty pharmaceutical companies commercializing their own products."

Ron Wooten, President, PharmaBio Development said: "We are pleased to be involved in the potential commercialization of Surfaxin(R), which represents the next generation surfactant product, with its broad application in the areas of MAS and RDS. This alliance is yet another example of how Quintiles' commercialization services and our PharmaBio Development group create strategic and financial solutions to help bring important new medicines to market. We are excited that our financial resources and commercial expertise can play a part in introducing Surfaxin(R) to the healthcare community."

This agreement follows a sequence of investment and royalty or commission-based agreements between Quintiles and emerging pharma and biotechnology companies. Quintiles plans to immediately initiate pre-market assessment and readiness under the agreement.

About Quintiles Transnational, PharmaBio and Innovex

Quintiles Transnational Corp. is the world's leading provider of information, technology and services to bring new medicines to patients faster and improve healthcare. Headquartered near Research Triangle Park, North Carolina, Quintiles Transnational is a member of the S&P 500 and Fortune 1000. For more information visit the company's Web site at www.quintiles.com. PharmaBio Development is the corporate ventures group of Quintiles Transnational Corp. that is dedicated to innovative partnering solutions for pharmaceutical and biotech companies.

Innovex is the world's leading commercial solutions provider that offers sales and marketing services designed to accelerate the success of pharmaceutical, biotech and medical device products. These services include contract sales services, strategic marketing solutions, customized information technologies and health management services. For more information, visit www.innovex.com.

Information in this press release contains "forward-looking statements" regarding Quintiles that involve risks and uncertainties that could cause actual results to differ materially, including without limitation, the risk that the market for our products and services will not grow as we expect, the risk that PharmaBio transactions will not generate revenues or profit at the rate or levels we anticipate, the risk that Discovery may not obtain FDA approval for Surfaxin(R), our

ability to efficiently distribute backlog among therapeutic business units and match demand to resources, actual operating performance, the ability to maintain large client contracts or to enter into new contracts, changes in trends in the pharmaceutical industry, and the ability to operate successfully in new lines of business. Additional factors that could cause actual results to differ materially are discussed in the company's recent filings with the Securities and Exchange Commission, including but not limited to its Annual Report on Form 10-K, its Form 8-Ks, and its other periodic reports, including Form 10-Qs.

About Discovery Laboratories and Surfaxin(R)

Discovery Laboratories Inc. is a Pennsylvania-based bio-pharmaceutical company whose mission is to develop and commercialize medically novel therapeutics for critical care. Presently, Discovery has four late stage clinical trials of Surfaxin(R) underway. Surfaxin(R) is the subject of a landmark Phase III pivotal clinical trial in respiratory distress syndrome (RDS) in pre-mature newborns as well as a second supportive Phase III trial. Surfaxin(R) is also the subject of a pivotal Phase III clinical trial in meconium aspiration syndrome (MAS) in full-term newborns. In addition, Discovery is conducting a Phase II clinical trial in acute respiratory distress syndrome (ARDS) in adults in the United States. MAS and ARDS are diseases for which there are no approved therapies anywhere in the world. More information about Discovery is available on the company's Web site at www.discoverylabs.com.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy any shares of Common Stock. To the extent that statements in this press release are not strictly historical, including statements as to the Company's business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Among the factors which could affect the Company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements, risks relating to the progress of the Company's research and development and the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in the Company's periodic filings with the Securities and Exchange Commission including the most recent reports on Form 10-KSB, 8-K and 10-QSB, and amendments thereto.

Statements in this press release regarding Quintiles and Discovery have been made by each respective company and is that company's sole responsibility.