

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended September 30, 2004

OR

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

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3171943

(I.R.S. Employer Identification No.)

350 South Main Street, Suite 307

Doylestown, Pennsylvania

(Address of principal executive offices)

18901

(Zip Code)

(215) 340-4699

(Registrants' telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 5, 2004, 47,029,529 shares of common stock, par value \$.001 per share, were outstanding.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc. (“Discovery”), and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc.

Safe Harbor Statement Under the Private Securities Litigation Act of 1995

Certain statements set forth in this report and any that are incorporated by reference herein which are not historical, including, without limitation, statements concerning our research and development programs and clinical trials, the possibility of submitting regulatory filings for our products under development, the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products, the research and development of particular compounds and technologies and the period of time for which our existing resources will enable us to fund our operations, constitute “Forward Looking Statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; delays in our preparation and filing of applications for regulatory approval; delays in the FDA’s or other health regulatory authorities’ approval or potential rejection of any applications we file, including the New Drug Application (NDA) we filed in April 2004 and the Marketing Approval Application (MAA) we submitted in October 2004; risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance filed by us for any such drug product; possible changes in our financial condition; the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin[®], or other drug candidates will not prove to be safe or useful for the treatment of certain indications); clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators (including strategic alliances for our aerosol and Surfactant Replacement Therapies) and the failure of collaborators to perform under their agreements with us; risk that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all; risk that the Company’s internal sales and marketing organization will not succeed in developing market awareness of the Company’s products; risk that the Company’s internal sales and marketing organization will not be able to attract or maintain qualified personnel; risks relating to the development of competing therapies and/or technologies by other companies; the progress of the regulatory approvals in connection with the conduct of our clinical trials and the marketing of our products; and the additional costs and delays which may result from requirements imposed by the health regulatory authorities in connection with obtaining the required approvals. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and other risks and uncertainties are detailed in Part I, Item 2:

“Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in any documents incorporated by reference in this report.

Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY **Condensed Consolidated Balance Sheets**

	September 30, 2004	December 31, 2003
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 22,160,000	\$ 29,422,000
Restricted cash	650,000	--
Available-for-sale marketable securities	10,673,000	--
Note receivable – current portion	2,000	3,000
Prepaid expenses and other current assets	1,383,000	665,000
	<hr/>	<hr/>
Total Current Assets	34,868,000	30,090,000
Property and equipment, net of accumulated depreciation	2,916,000	2,414,000
Note receivable, net of current portion	191,000	192,000
Other assets	1,616,000	19,000
	<hr/>	<hr/>
Total Assets	<u>\$ 39,591,000</u>	<u>\$ 32,715,000</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,218,000	\$ 4,210,000
Line of Credit	5,683,000	2,436,000
Capitalized lease – current portion	643,000	383,000
	<hr/>	<hr/>
Total current liabilities	10,544,000	7,029,000
Deferred revenue	269,000	672,000
Capitalized lease, net of current portion	1,334,000	711,000
	<hr/>	<hr/>
Total Liabilities	12,147,000	8,412,000
Stockholders' Equity:		
Common stock, \$.001 par value; 80,000,000 authorized; 47,021,413 and 42,491,438 issued and outstanding at September 30, 2004 and December 31, 2003, respectively	47,000	43,000
Additional paid-in capital	153,984,000	122,409,000
Unearned portion of compensatory stock options	(519,000)	(2,000)
Accumulated deficit	(123,009,000)	(96,858,000)
Treasury stock (at cost; 313,383 and 167,179 shares at September 30, 2004 and December 31, 2003, respectively)	(3,054,000)	(1,289,000)
Accumulated other comprehensive loss	(5,000)	--
	<hr/>	<hr/>
Total Stockholders' Equity	27,444,000	24,303,000
	<hr/>	<hr/>
Total Liabilities & Stockholders' Equity	<u>\$ 39,591,000</u>	<u>\$ 32,715,000</u>

PART I - FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****DISCOVERY LABORATORIES, INC. AND SUBSIDIARY****Condensed Consolidated Statements of Operations
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues:				
Contracts, Licensing, Grants & Milestones	\$ 236,000	\$ 198,000	\$ 1,075,000	\$ 855,000
Expenses:				
Research & Development	5,673,000	5,096,000	18,757,000	12,950,000
General & Administrative	2,908,000	1,375,000	8,363,000	3,679,000
Total Expenses	<u>8,581,000</u>	<u>6,471,000</u>	<u>27,120,000</u>	<u>16,629,000</u>
Operating Loss	(8,345,000)	(6,273,000)	(26,045,000)	(15,774,000)
Other income and expenses:				
Interest income, dividends, realized gains, and other income	284,000	116,000	555,000	382,000
Interest and amortization expense	<u>(321,000)</u>	<u>(62,000)</u>	<u>(661,000)</u>	<u>(181,000)</u>
Net Loss	<u>\$ (8,382,000)</u>	<u>\$ (6,219,000)</u>	<u>\$ (26,151,000)</u>	<u>\$ (15,573,000)</u>
Net loss per common share – basic and diluted	\$ (0.18)	\$ (0.15)	\$ (0.57)	\$ (0.43)
Weighted average number of common shares outstanding – basic and diluted	46,987,545	41,084,355	45,659,485	35,809,252

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Condensed Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	\$ (26,151,000)	\$ (15,573,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	614,000	272,000
Compensatory stock options	647,000	104,000
Changes in:		
Prepaid expenses and other current assets	(766,000)	(579,000)
Accounts payable and accrued expenses	8,000	625,000
Other assets	(74,000)	(1,000)
Amortization of deferred revenue	(403,000)	(541,000)
Net cash used in operating activities	<u>(26,125,000)</u>	<u>(15,693,000)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(894,000)	(861,000)
Restricted cash	(650,000)	--
Related party loan payments received	2,000	1,000
Purchase of marketable securities	(18,344,000)	(271,000)
Proceeds from sale or maturity of marketable securities	<u>7,444,000</u>	<u>7,513,000</u>
Net cash (used in) provided by investing activities	<u>(12,442,000)</u>	<u>6,382,000</u>
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	28,940,000	33,510,000
Proceeds from credit facility	3,247,000	615,000
Proceeds from capital lease arrangement	1,237,000	480,000
Purchase of treasury stock	(1,765,000)	(1,050,000)
Principal payments under capital lease obligation	<u>(354,000)</u>	<u>(175,000)</u>
Net cash provided by financing activities	<u>31,305,000</u>	<u>33,380,000</u>
Net (decrease) increase in cash and cash equivalents	(7,262,000)	24,069,000
Cash and cash equivalents – beginning of period	<u>29,422,000</u>	<u>8,538,000</u>
Cash and cash equivalents - end of period	<u>\$ 22,160,000</u>	<u>\$ 32,607,000</u>
Supplementary disclosure of cash flows information:		
Interest paid	\$ 101,000	\$ 144,000
Non-cash transactions:		
Class H warrants issued/revalued	(48,000)	--
Deferred debt issuance costs	1,523,000	--
Unrealized loss on marketable securities	(5,000)	(123,000)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 – THE COMPANY AND BASIS OF PRESENTATION

The Company

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our technology produces a precisely engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. We believe that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

We have filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, our lead product, for the prevention and treatment of RDS in premature infants. We are also conducting various clinical programs to address ARDS in adults, BPD, a form of chronic lung disease in premature infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and MAS in full-term infants.

We are presently implementing a long-term commercial strategy which includes manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, and sales and marketing capabilities to execute the launch of Surfaxin, if approved, in the U.S. and Europe.

Stock Based Employee Compensation

The Financial Accounting Standards Board has issued Statement of Financial Accounting Standards (“SFAS”) No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosure”. SFAS No. 148 amends SFAS No. 123, “Accounting for Stock-Based Compensation” to provide alternative methods of transition to a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on the reported results. We continue to account for our stock option plans in accordance with Accounting Principles Board Opinion No. 25, “Accounting for Stock Options Issued to Employees” and, accordingly, recognize compensation expense for the difference between the fair value of the underlying shares of common stock and the exercise price of the option at the date of grant. The effect of applying SFAS No. 148 on pro forma net loss is not necessarily representative of the effects on reported net income or loss for future years due to, among other things, (i) the vesting period of the stock options and (ii) the fair value of additional stock options in future years.

If the methodology prescribed under SFAS No. 148 had been used to determine the fair value of the stock options, then the pro forma net loss for the periods ended September 30, 2004 and 2003 would have been as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net Loss as Reported	\$ (8,382,000)	\$ (6,219,000)	\$ (26,151,000)	\$ (15,573,000)
Additional stock-based employee compensation	<u>\$ (956,000)</u>	<u>\$ (3,475,000)</u>	<u>\$ (3,378,000)</u>	<u>\$ (4,486,000)</u>
Pro forma net loss	<u>\$ (9,338,000)</u>	<u>\$ (9,694,000)</u>	<u>\$ (29,529,000)</u>	<u>\$ (20,059,000)</u>
Pro forma net loss per share	\$ (0.20)	\$ (0.24)	\$ (0.65)	\$ (0.56)

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine-month periods ended September 30, 2004, are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2003.

All of our current products under development are subject to license agreements that will require the payment of future royalties.

A reclassification has been made to the presentation of operating expenses in the current fiscal year. The expense associated with a milestone payment related to the license of Surfaxin has been reclassified from general and administrative expenses and is currently reflected in research and development expenses. In addition, Certain prior year balances have been reclassified to conform with the current presentation.

NOTE 2 – NET LOSS PER SHARE

Net loss per share is computed based on the weighted average number of common shares outstanding for the periods. Common shares issuable upon the exercise of options and warrants are not included in the calculation of the net loss per share as their effect would be anti-dilutive.

NOTE 3 – COMPREHENSIVE LOSS

Total comprehensive loss was approximately \$8,369,000 and \$26,157,000 for the three and nine months ended September 30, 2004, respectively, and approximately \$6,294,000 and \$15,696,000 for the three and nine months ended September 30, 2003, respectively.

NOTE 4 – NOTE RECEIVABLE

Note receivable pertains to a \$200,000, 7% per annum mortgagor's note due from one of our executive officers. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly

payments of principal and interest over a 360-month period. The principal balance outstanding at September 30, 2004 and December 31, 2003 was approximately \$193,000 and \$195,000, respectively.

NOTE 5 – TREASURY STOCK

During the nine months ended September 30, 2004, certain members of our management and certain consultants, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tendered shares of common stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the nine months ended September 30, 2004, 146,204 shares of our common stock were tendered to us by such parties in lieu of cash at a weighted average price of \$12.07 per share. These shares are accounted for as treasury stock as follows:

	Number of shares received in lieu of cash for the exercise of stock options	Weighted average price per share
January 2004	97,226	\$12.44
March 2004	18,497	12.08
May 2004	24,702	11.27
July 2004	5,779	9.30
Total	146,204	\$12.07

NOTE 6 – RESTRICTED CASH

We have entered into a lease agreement for 39,594 square feet of office space in Bucks County, Pennsylvania, which will serve as the company headquarters and as the main operating facility for clinical development, regulatory, and sales and marketing. Subject to the terms and conditions of the lease, aggregate payments for this lease will be approximately \$4.6 million over the five-year term.

In connection with the lease agreement for the new office space in Bucks County, Pennsylvania, we established a security deposit in the amount of \$600,000 in the form of a letter of credit. The letter of credit is secured by cash and is included in the Balance Sheet as “Restricted Cash”. Beginning on the first day of the 40th month of the lease term, the security deposit and the letter of credit will be reduced by \$200,000 to \$400,000, with such reduction becoming available for use by the Company. That balance will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease, the letter of credit will expire and such cash will be available for use by the Company.

Our current facilities, located in Doylestown, Pennsylvania are subject to various lease agreements, which expire in November 2004, March 2005 and August 2005. We intend to maintain a portion of the current facility for the continuation of analytical laboratory activities and to sublease the remaining portions of the current facility to the greatest extent possible. To the extent subleasing is not possible, the leases will expire according to their terms.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Since our inception, we have incurred significant losses and, as of September 30, 2004, we had an accumulated deficit of approximately \$123 million. The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, business and commercial development, financial, legal and general corporate activities. See "Results of Operations".

We have funded our operations with working capital provided principally through public and private equity financings and strategic collaborations. As of September 30, 2004, we had cash and investments of approximately \$33.5 million, an \$8.5 million secured revolving credit facility with PharmaBio Development, Inc., a subsidiary of Quintiles Transnational Corp., of which \$5.7 million was outstanding, and a \$4.0 million capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), of which approximately \$1.7 million was available for borrowing, \$2.3 million had been used, and \$1.9 million was outstanding.

In November 2004, the credit facility with Quintiles was extended and our capital lease financing with GECC was expanded. See "Liquidity and Capital Resources".

Research and Development

Research and development expenses for three and nine months ended September 30, 2004 were \$5,673,000 and \$18,757,000, respectively. Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. Our research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations, and other direct clinical trials activities. These cost categories typically include the following expenses:

Research and Pre-Clinical Operations

Research and pre-clinical operations reflect activities associated with research prior to the initiation of any potential human clinical trials. These activities predominantly represent projects associated with the development of aerosolized formulations of our precision-engineered lung surfactant and aerosol delivery systems to potentially treat a range of respiratory disorders prevalent in the NICU and the hospital. Research and pre-clinical operations costs primarily reflect expenses incurred for personnel, consultants, facilities and research and development arrangements with The Scripps Research Institute.

Manufacturing Development

Manufacturing development primarily reflects costs incurred to prepare current good manufacturing procedures (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. These costs primarily reflect activities with external contract manufacturing resources. Included in manufacturing development are personnel costs, depreciation, expenses associated with

technology transfer, process development and validation, quality control and assurance activities, and analytical services.

Unallocated Development -- Clinical and Regulatory Operations

Clinical and regulatory operations reflect the preparation, implementation, and management of our clinical trial activities in accordance with current good clinical practice (cGCP). Included in unallocated clinical development and regulatory operations are costs associated with personnel, supplies, facilities, fees to consultants, other related costs for clinical trial implementation and management, clinical quality control, regulatory compliance activities, data management and biostatistics.

Direct Expenses -- Clinical Trials

Direct expenses of clinical trials includes patient enrollment costs, external site costs, expense of clinical drug supply, and external costs such as contract research consultant fees and expenses.

The following summarizes our research and development expenses by the foregoing categories for the three and nine months ended September 30, 2004:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Research and Development Expenses:				
Research and pre-clinical operations	\$728	\$539	\$2,030	\$ 1,375
Manufacturing development	1,069	1,274	4,632	1,817
Unallocated development - clinical and regulatory operations	1,904	1,453	6,150	3,987
Direct clinical trial expenses	1,972	1,830	5,945	5,771
Total Research and Development Expenses	\$ 5,673	\$ 5,096	\$ 18,757	\$ 12,950

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical development or pre-clinical development. The status and anticipated completion dates of each of our lead SRT programs is discussed in “Plan of Operations,” below. Successful completion of development of our SRT is contingent on numerous risks, uncertainties, and other factors, which are described in detail in the section entitled “Risk Related to our Business”. These factors include:

- Completion of pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval
- Receipt of necessary regulatory approvals
- Obtaining adequate supplies of surfactant raw materials on commercially reasonable terms
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials

- Performance of third-party collaborators on whom we rely heavily for the commercialization and manufacture of Surfaxin
- Obtaining manufacturing, sales and marketing capabilities for which we presently have limited resources.

As a result of the amount and nature of these factors, many of which are outside our control, the success, timing of completion, and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- Slow patient enrollment
- Long treatment time required to demonstrate effectiveness
- Lack of sufficient clinical supplies and material
- Adverse medical events or side effects in treated patients
- Lack of effectiveness of the product candidate being tested
- Lack of sufficient funds

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and the value of our company and our financial condition and results of operations will be substantially harmed.

Plan of Operations

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products, manufacturing, commercialization, and general and administrative activities.

We anticipate that during the next 12 to 24 months we will:

- increase our research, development and regulatory activities in an effort to develop a broad pipeline of potential SRT for respiratory diseases. The drug development, clinical trial, and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in the “Risks Related to Our Business” - “Our technology platform is based solely on our proprietary precision-engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement therapies may be delayed, or fail, which will harm our business”; - “The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.” Our major research and development projects include:

SRT for Neonatal Intensive Care indications

We are in a Phase 2 clinical trial for the prevention of meconium aspiration syndrome (MAS) in full-term infants and expect to complete this trial in 2005. We are preparing to initiate a Phase 2 clinical trial late in the fourth quarter of 2004 using aerosolized SRT via nasal continuous positive airway pressure (nasal CPAP) to treat premature infants in the NICU suffering from neonatal respiratory failure. We are also preparing to initiate a Phase 2 clinical trial in the first quarter of 2005 using Surfaxin for the prevention of Bronchopulmonary Dysplasia (BPD). We expect both of these trials to be completed in the second half of 2005.

SRT for Critical Care and Hospital indications

For Acute Respiratory Distress Syndrome in adults, we currently are conducting a Phase 2 dose-ranging safety and efficacy study of up to 110 patients in the United States. We expect to complete this trial in late 2004. We are preparing to initiate a Phase 2 clinical trial late in 2004 or early in 2005 for patients with moderate to severe asthma (development name DSC-104).

In addition, we are evaluating the development of aerosolized formulations of our precision-engineered surfactant to potentially treat Acute Lung Injury, COPD, rhinitis, sinusitis, sleep apnea and otitis media (inner ear infection).

- (ii) invest in marketing and commercialization (including distribution) resources to execute the launch of Surfaxin, if approved, for the treatment of Respiratory Distress Syndrome in premature infants and the execution of our worldwide sales and marketing strategy. Significant investment will be required as we build our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings.
- (iii) invest in and support a long-term manufacturing strategy for the production of our precision-engineered surfactant drug product including further development of our current contract manufacturer, and evaluating and establishing additional contract or Discovery-owned manufacturing facilities in order to secure additional manufacturing capabilities to meet production needs as they expand.
- (iv) invest in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

Through our contract manufacturer, Laureate Pharma, L.P., we have established a Surfaxin manufacturing line to support the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). This arrangement provides for the commercial-scale requirements of Surfaxin for the prevention of RDS in premature infants and all of our anticipated clinical-scale production requirements including Surfaxin for the treatment of ARDS in adults. In addition to our arrangement with Laureate, we plan to conduct other activities in connection with the implementation of our long term manufacturing strategy including evaluating and establishing additional contract or Discovery-owned manufacturing facilities. See “Risks Related to Our Business” – “In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product which may not be readily available” and “If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products”.

On November 3, 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate the commercialization agreements for Surfaxin in the United States. We will now have full commercialization rights for Surfaxin in the United States. Under the agreement signed in 2001, Quintiles would have provided commercialization services for seven years post-launch, with an obligation to fund such services up to \$10 million per year. Our obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of respiratory distress syndrome (RDS) and MAS for 10 years following launch is terminated. We have entered into a three-year limited preferred-

provider arrangement with Quintiles. See “Risks Related to our Business” – “We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates” and “We may be unable to either establish marketing and sales capabilities or enter into corporate collaborations necessary to successfully commercialize Surfaxin or our other potential products.”

In connection with obtaining full commercialization rights for Surfaxin, we have issued 850,000 warrants to PharmaBio Development Inc., Quintiles’ strategic investment group, to purchase shares of our common stock at an exercise price equal to \$7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to us if exercised equal to approximately \$6 million. We expect to take a charge against earnings equal to approximately \$4 million for the fourth quarter of 2004 in connection with the issuance of such warrants. The existing secured revolving credit facility of \$8.5 million with PharmaBio, will remain available to us and the original maturity date of December 10, 2004 is now extended until December 31, 2006. Amounts to be drawn down under the credit facility will remain available up to the date of the commercial launch of Surfaxin.

We have a strategic alliance with Laboratorios del Dr. Esteve S.A. to develop, market and sell Surfaxin throughout Europe and Latin America. Esteve will provide certain commercialization services for Surfaxin for the prevention of RDS in premature infants, MAS in full-term infants and ARDS/ Acute Lung Injury (ALI)/ in adult patients. Our exclusive supply agreement with Esteve provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve will pay certain clinical trial costs related to obtaining regulatory approval in Europe for the indications of ALI/ARDS and will make certain milestone payments to us upon the attainment of European marketing regulatory approval for Surfaxin.

We will need to generate significant revenues from product sales and or related royalties and transfer prices to achieve and maintain profitability. Through September 30, 2004, we had not generated any revenues from any product sales, and had not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and third party contract manufacturers and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2003, we had not generated taxable income. On December 31, 2003, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$91.6 million. The future utilization of such loss carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of \$1.9 million. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2021.

Results of Operations

Net loss for the three and nine months ended September 30, 2004 were \$8,382,000 (\$0.18 per common share) and \$26,151,000 (\$0.57 per common share), respectively. Net loss for the three and nine months

ended September 30, 2003 were \$6,219,000 (\$0.15 per common share) and \$15,573,000 (\$0.43 per common share), respectively.

Revenues

Revenues from research and development collaborative agreements and grants for the three and nine months ended September 30, 2004 were \$236,000 and \$1,075,000, respectively. Revenues from research and development collaborative agreements and grants for the three and nine months ended September 30, 2003 were \$198,000 and \$855,000, respectively. These revenues are associated with our alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America (whereby Esteve funded a portion of the RDS clinical trial costs and has committed to fund up to \$6 million of ARDS development costs) as well as a Small Business Innovative Research (SBIR) grant, which was concluded in 2003, to develop Surfaxin for ALI/ARDS in adults. The amounts recognized for the three and nine months ending September 30, 2004, primarily reflects revenue recognized pursuant to Esteve's ARDS development commitment. Revenues recognized for the three and nine months ending September 30, 2003, primarily reflect work activities pursuant to the SBIR grant for research of ALI/ARDS treatments and revenue recognized in connection with Esteve's funding of the RDS clinical trial costs.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2004 were \$5,673,000 and \$18,757,000, respectively. Research and development expenses for the three and nine months ended September 30, 2003 were \$5,096,000 and \$12,950,000, respectively.

The increase in research and development expenses for the three and nine months ended September 30, 2004, compared to the same periods last year, primarily reflects:

- (i) \$1,069,000 and \$4,632,000, for the three and nine months ended September 30, 2004, respectively, for manufacturing activities to support the production of clinical and commercial drug supply of Surfaxin at Laureate's facility in conformance with cGMPs. Costs associated with manufacturing activities for the three and nine months ended September 30, 2003 were \$1,274,000 and \$1,817,000, respectively;
- (ii) development activities, including drug supply, for the Phase 2 clinical trial of Surfaxin for the treatment of ARDS in adults;
- (iii) development and regulatory efforts for Surfaxin - primarily the Phase 3 clinical trials for Surfaxin for the prevention of RDS in premature infants for which an NDA was filed with the FDA in April 2004 and an MAA was submitted with the EMEA in October 2004; and
- (iv) research and development activities of aerosolized formulations of the Company's SRT technology.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2004 were \$2,908,000 and \$8,363,000, respectively. General and administrative expenses for the three and nine months ended September 30, 2003 were \$1,375,000 and \$3,679,000, respectively. General and

administrative expenses consist primarily of the costs of executive management, business and commercial development, financial and accounting, legal, facility and other administrative costs.

The increase in general and administrative expenses for the three and nine months ended September 30, 2004 primarily reflects:

- (i) pre-launch commercialization services for RDS of approximately \$1,317,000 and \$3,327,000, respectively for the three and nine months ended September 30, 2004 compared to \$307,000 and \$617,000, respectively, for the same periods last year. For the three and nine months ended September 30, 2004, \$872,000 and \$2,546,000, respectively, of the pre-launch commercialization costs were incurred pursuant to the collaboration agreement with Quintiles (for which funding is provided by the secured, revolving credit facility with PharmaBio, discussed below in “Liquidity and Capital Resources”);
- (ii) financial and information technology capabilities in preparation for the potential approval and launch of Surfaxin for RDS;
- (iii) corporate governance and other regulatory compliance initiatives in light of the Sarbanes-Oxley Act and other recent regulatory changes concerning public companies generally; and
- (iv) legal activities related to the preparation and filing of patents and other activities associated with our intellectual property in connection with the expansion of our SRT pipeline.

Other Income and Expense

Interest income for the three and nine months ended September 30, 2004 was \$284,000 and \$555,000 respectively as compared to \$116,000 and \$382,000 respectively for the three and nine months ended September 30, 2003. The increase in interest income is primarily due to a higher average cash, cash equivalent and marketable securities balance.

Interest expense and amortization expense for the three and nine months ended September 30, 2004 was \$321,000 and \$661,000 respectively as compared to \$62,000 and \$181,000 respectively for the three and nine months ended September 30, 2003. The increase is primarily due to interest expense associated with our secured, revolving credit facility, and capital lease financing arrangements. See “Liquidity and Capital Resources”.

Liquidity and Capital Resources

Cash, Cash Equivalents, and Marketable Securities

As of September 30, 2004, we had cash, cash equivalents, restricted cash and marketable securities of approximately \$33.5 million as compared to approximately \$29.4 million as of December 31, 2003. The increase from December 31, 2003, is primarily due to: (i) an underwritten public offering of 2,200,000 shares of common stock with gross and net proceeds equal to \$24.2 million and approximately \$22.7 million, respectively; (ii) \$4.3 million received from the exercise of outstanding options and warrants; and (iii) \$4.5 million from our secured, revolving credit facility and capital lease financing arrangements. These increases were offset by \$26.1 million used in operating activities during the period.

For the quarter ended September 30, 2004, cash and marketable securities decreased \$7.8 million due to the use of approximately \$9.0 million for operating and investing activities offset by \$1.2 million of net proceeds from the use of existing credit and capital lease facilities.

Committed Equity Financing Facility (CEFF)

In July 2004, we entered into a CEFF with Kingsbridge Capital Ltd., pursuant to which Kingsbridge committed to finance up to \$75 million of capital to support our future growth. Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of our common stock and thus raise capital as required, at the time, price and in amounts deemed suitable to us. As of September 30, 2004, we had not been permitted to utilize the CEFF as the SEC had yet to declare effective the resale registration statement required by the terms of the CEFF. This registration statement was declared effective by the SEC in November, 2004. Accordingly, subject to the other conditions and limitations contained in the CEFF, we are now free to utilize the potential resources afforded to us by the CEFF. Depending on market conditions and our financing needs, we currently expect that we may begin to utilize a portion of the CEFF during the fourth quarter of 2004 in order to provide working capital and to fund our commercialization and research and development efforts, primarily for the build-out and control of our own sales and marketing operation.

Secured Revolving Credit Facility and Capital Lease Financing Arrangements

We have a secured revolving credit facility of up to \$8.5 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. On November 3, 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate the commercialization agreements for Surfaxin in the United States. The existing secured revolving credit facility of \$8.5 million with PharmaBio will remain available to us such that we may borrow up to \$8.5 million on a revolving basis until the earlier to occur of either May 15, 2005 or the date that Surfaxin is first shipped for commercial sale for MAS or RDS. The original maturity date of December 10, 2004, is now extended until December 31, 2006. Interest on amounts advanced under the PharmaBio credit facility is payable quarterly in arrears. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006. As of September 30, 2004, \$5.7 million was outstanding under the credit facility. Our use of this credit facility was \$0.9 million and \$3.2 million for the three and nine months ended September 30, 2004, respectively. By virtue of the termination of the commercialization agreements, we are no longer obligated to use funds advanced under the credit facility for services provided by Quintiles and PharmaBio is no longer obligated to make milestone payments to us that could be used to offset and prepay such advances. The descriptions of the restructured arrangements with Quintiles and PharmaBio in this report do not purport to be complete and are qualified in their entirety by reference to the relevant agreements and instruments attached as exhibits hereto.

We have a capital lease financing arrangement with the Life Science and Technology Finance Division of GECC. In November 2004, the arrangement was increased by \$6.5 million to provide, subject to certain conditions, up to an aggregate \$9.0 million in financing for capital purchases. Under the terms of the expanded financing arrangement, \$5 million is immediately available to us with the remaining \$1.5 million accessible upon FDA approval to market the Company's lead product Surfaxin, for the prevention of RDS in premature infants. We intend to use financial resources from the GECC capital lease arrangement to invest in additional information technology systems such as sales, materials requirements planning and medical safety monitoring to support our commercialization efforts. As of

September 30, 2004, approximately \$1.7 million was available for use and approximately \$1.9 million, net of principal payments, was outstanding under this financing arrangement. Use of this financing arrangement was \$371,000 and \$1,237,000 for the three and nine months ended September 30, 2004, respectively.

Lease Agreement

We have entered into a lease agreement for 39,594 square feet of office space in Bucks County, Pennsylvania, which will serve as the company headquarters and as the main operating facility for clinical development, regulatory, and sales and marketing. Subject to the terms and conditions of the lease, aggregate payments for this lease will be approximately \$4.6 million over the five-year term.

In connection with the lease agreement for the new office space in Bucks County, Pennsylvania, we established a security deposit in the amount of \$600,000 in the form of a letter of credit. The letter of credit is secured by cash and is included in the Balance Sheet as "Restricted Cash". Beginning on the first day of the 40th month of the lease term, the security deposit and the letter of credit will be reduced by \$200,000 to \$400,000, with such reduction becoming available for use by the Company. That balance will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease, the letter of credit will expire and such cash will be available for use by the Company.

Our current facilities, located in Doylestown, Pennsylvania are subject to various lease agreements, which expire in November 2004, March 2005 and August 2005. We intend to maintain a portion of the current facility for the continuation of analytical laboratory activities and to sublease the remaining portions of the current facility to the greatest extent possible. To the extent subleasing is not possible, the leases will expire according to their terms.

Working Capital

We believe our current working capital is sufficient to meet our planned activities through late in the second quarter of 2005, before taking into account any amounts that may be available through use of the CEFF. See "Committed Equity Financing Facility (CEFF)" above for a discussion of the possibility that we may begin to utilize the CEFF in the fourth quarter of 2004. We will need additional financing from investors or collaborators to complete research and development and commercialization of our current product candidates under development. Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, levels of resources that our collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors, our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Historically, our working capital has been provided from the proceeds of private financing and strategic alliances:

In July 2004, we entered into a CEFF with Kingsbridge pursuant to which Kingsbridge has committed to finance up to \$75.0 million of capital for newly-issued shares of common stock. The exact timing,

amount and price of any CEFF financings is subject to our ultimate determination, subject to certain conditions. See “Committed Equity Financing Facility (CEFF)”. In connection with the CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of common stock at an exercise price equal to \$12.0744 per share. The exercise term of the warrant is five years beginning with the six-month anniversary of the closing date of the agreement. The warrant must be exercised for cash, except in limited circumstances. As of September 30, 2004 all of the Class B Investor warrants were outstanding.

In April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at \$11.00 per share resulting in our receipt of gross and net proceeds equal to \$24.2 million and approximately \$22.7 million, respectively.

In December 2003, we filed a shelf registration statement with the SEC for the proposed offering from time to time of up to 6.5 million shares of our common stock. We have no immediate plans to sell the additional 4.3 million shares of common stock remaining under this shelf registration statement. However, we will be able to issue these securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

In June 2003, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$25.9 million. We issued 4,997,882 shares of common stock and 999,577 Class A Investor warrants to purchase shares of common stock at an exercise price equal to \$6.875 per share. The Class A Investor warrants have a seven-year term. As of September 30, 2004, all of the Class A Investor warrants were outstanding. As of September 30, 2004 945,745 of the Class A Investor warrants were outstanding.

In November 2002, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately \$11.9 million. We issued 6,397,517 shares of common stock and 2,878,883 Class I Warrants to purchase shares of common stock at an exercise price of \$2.425 per share. The Class I warrants had a five-year term and we were entitled to redeem the Class I warrants upon the attainment of certain exchange-related price performance thresholds of the common stock. In June 2003, the price performance criteria was met and we provided notice to the Class I warrant holders of our intention to redeem the Class I warrants. All of the Class I warrants have been exercised resulting in 2,506,117 shares issued and proceeds of approximately \$4.3 million.

Pursuant to our collaboration arrangement with Esteve on March 6, 2002, we issued 821,862 shares of common stock to Esteve at a purchase price equal to \$4.867 per share and received a licensing fee of \$500,000, for approximate net aggregate proceeds of \$4,450,000.

Pursuant to the original arrangements that we entered into with Quintiles and PharmaBio in December 2001, we issued to PharmaBio, for approximate net aggregate proceeds of \$2.7 million: (i) 791,905 shares of common stock at a price equal to \$3.79 per share; and (ii) Class G warrants to purchase 357,143 shares of common stock at an exercise price equal to \$3.485 per share (subject to adjustment). The Class G warrants had a ten-year term and we were entitled to redeem the Class G warrants upon the attainment of certain exchange-related price performance thresholds of the common stock. In February 2004, the price performance criteria was met and we provided notice to PharmaBio of our intention to redeem the Class G warrants. The Class G warrants were cashlessly exercised resulting in the issuance of 249,726 shares. In connection with the credit facility, we issued to PharmaBio Class H warrants to purchase 320,000 shares of common stock. The Class H warrants are exercisable at \$3.03 per share (subject to adjustment) and are exercisable proportionately only upon availability of the credit facility.

The Class H warrants had a 10-year term and we were entitled to redeem the Class H warrants upon the attainment of certain exchange-related price performance thresholds of the common stock. In April 2004, the price performance criteria was met and we provided notice to PharmaBio of our intention to redeem the vested portion of the Class H warrants. As of June 30, 2004, the vested portion of the Class H warrants were cashlessly exercised resulting in the issuance of 160,318 shares. Subsequently, on August 4, 2004, the remaining Class H warrants vested, were redeemed and cashlessly exercised resulting in the issuance of 68,084 shares.

In October 2001, we received approximately \$7.3 million in net proceeds from a private financing. In the financing, we issued 3,562,759 shares of common stock and 712,553 Class F warrants to purchase shares of common stock at an exercise price of \$2.365 per share. The Class F warrants had a five-year term and we were entitled to redeem the Class F warrants, with 20 days' prior written notice, for \$.001, upon the attainment of certain exchange-related price performance thresholds of the common stock. In July 2003, the price performance criteria was met and we provided notice to the Class F warrant holders of our intention to redeem the Class F warrants. All Class F warrants have been exercised resulting in 712,553 shares issued and proceeds of approximately \$1.7 million.

In April 2001, we received approximately \$1.0 million in proceeds in a private offering of 296,560 shares of common stock at a per share price equal to \$3.37.

Risks Related to Our Business

The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time.

Because we are a biopharmaceutical company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a biopharmaceutical company, therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of September 30, 2004, we have an accumulated deficit of approximately \$123 million and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary precision-engineered, engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business.

Our precision-engineered surfactant platform technology is based on the scientific rationale of SRT to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently, we completed and filed an NDA with the FDA and an MAA with the EMEA based on results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the prevention of RDS in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and a Phase 2 trial for the prevention of MAS in full-term infants. We are preparing for the initiation of a Phase 2 clinical trial using aerosolized SRT via nasal CPAP to potentially treat premature infants in the NICU suffering from neonatal respiratory failures, a Phase 2 clinical trial using Surfaxin for the prevention of Bronchopulmonary Dysplasia (BPD), and a Phase 2 trial using DSC-104 to treat patients with moderate to severe asthma.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

We will need additional capital and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available financial resources will be adequate to satisfy our capital needs into the second half of 2005. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge, the credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See "Risks Related to our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders".

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to our Business - The market price of our stock may be adversely affected by market volatility".

Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

There are 15,375,000 shares of our common stock that are reserved for issuance under the CEFF arrangement with Kingsbridge, 375,000 of which are issuable under the warrant we granted to Kingsbridge. The issuance of shares of our common stock under the CEFF and upon exercise of the warrant will have a dilutive impact on other stockholders of the Company and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Kingsbridge sells shares of our common stock issued under the CEFF to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or either similar transactions. This could contribute to a decline in the stock price of our common stock.

We may not be able to meet the conditions we are required to meet under CEFF and we may not be able to access any portion of the \$75.0 million available under the CEFF. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and comparable agencies in foreign countries that the manufacturer of the product maintains good laboratory

and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA or EMEA may not accept or approve an NDA or MAA filed by a pharmaceutical or biotechnology company for such drug product. On April 13, 2004, we filed an NDA for Surfaxin for the prevention of RDS in premature infants. The FDA accepted the NDA filing and has established February 13, 2005 as a target date for completion of the review. However, the FDA may not complete the review by such time or may reject the NDA. We have also submitted an MAA with the EMEA for clearance to market Surfaxin for the prevention and treatment of RDS in premature infants. The EMEA has validated the MAA indicating that the application is complete and that the review process has begun. However, the EMEA may not complete the review or may reject the MAA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 2005, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our precision-engineered surfactant-based therapy, MAS in full-term infants and ARDS in adults, have been granted designation as “fast-track” products under provisions of the Food and Drug Administration Modernization Act of 1997. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: ARDS in adults; RDS in infants; and MAS in full-term infants. To support our development of Surfaxin for the treatment of MAS, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA’s review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years.

The EMEA has granted Orphan Medicinal Product designation for three of our intended indications for Surfaxin; RDS in premature infants, MAS in full-term infants and ALI in adults.

Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain, if any. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. Laureate, our contract manufacturer, may not be able to produce Surfaxin to appropriate standards for use in clinical studies. A failure by Laureate to do so may delay or impair our ability to obtain regulatory approval for Surfaxin. See also “Risks Related to our Business - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.”

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, Laureate is our sole clinical manufacturing facility that has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies.

Laureate or other outside manufacturers may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing agreements with us or (iii) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing

equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practices (cGMPs) or similar requirements that the FDA or corresponding foreign regulators establish. Manufacturing or quality control problems could occur at the contract manufacturers causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's current cGMP requirements necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have a collaboration arrangement with Esteve for Surfaxin covering all of Europe and Latin America. Esteve will be responsible for the marketing of Surfaxin for the prevention/treatment of RDS in premature infants, MAS in full-term infants and ALI/ARDS in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining EMEA approval for commercialization of Surfaxin in Europe for the indications of ALI/ARDS. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to EMEA filings.

If Esteve or us breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to our Business – We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require

us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.”

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical Corporation, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or

additional patents may not be issued to us. See also “Risks Related to our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

Intellectual property rights of third parties could limit our ability to market our products.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality

agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- they will breach these agreements;
- any agreements we obtain will not provide adequate remedies for the applicable type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
- our competitors will independently discover our proprietary information and trade secrets.

We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

If we successfully develop and obtain regulatory approval for Surfaxin and the other product candidates that we are currently developing, we may: (1) market and sell them through our sales force, (2) license some of them to large pharmaceutical companies and/or (3) market and sell them through other arrangements, including co-promotion arrangements.

We plan to develop our marketing and sales team as we expect to rely primarily on such team to market Surfaxin in the United States, if Surfaxin is approved by the FDA. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we cannot assure you that we will be able to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Additionally, we may not be able to provide adequate incentive to our sales force. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

Developing a marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process. We have no prior experience developing a marketing and sales team and may be unsuccessful in our attempt to do so. If we are unable to develop an internal sales and marketing operation, we may not be able to increase market awareness and sell our products.

Establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. We expect to incur significant expenses in developing our marketing and sales team. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we cannot assure investors that we will have the funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

We may also need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our sales force and incur additional costs.

We may also rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully develop a marketing and sales team or to enter

into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Dependence on distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including:

- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products thereby exposing us to potential expenses in terminating such distribution agreements; and
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties in a timely manner or if they fail to perform, it could adversely affect sales of our products. We and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the providing of incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing our sales.

We may be unable to either establish marketing and sales capabilities or enter into corporate collaborations necessary to successfully commercialize Surfaxin or our other potential products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing and sales resources. To achieve commercial success for Surfaxin, or any other approved product, we must either rely upon our limited marketing and sales force and related infrastructure, or enter into arrangements with others to market and sell our products. We are promoting Surfaxin in the United States through our own dedicated marketing and sales team. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we cannot assure you that we will be able to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

In addition, establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. Our ability to make that investment and also execute our current operating plan and attain profitability by 2006 is dependent on numerous factors, including, as described above, partnering of clinical programs at opportune times and continued prudent fiscal management. Accordingly, we cannot assure investors that we will have the funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

Moreover, Surfaxin competes, and our product candidates in development are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales

operations. Because these companies are capable of devoting significantly greater resources to their marketing and sales efforts, our marketing and sales efforts may not compete successfully against the efforts of these other companies.

We have also announced our intention to market and sell Surfaxin outside of the United States through one or more marketing partners upon receipt of approval abroad. Although our agreement with Esteve provides for collaborative efforts in directing a global commercialization effort, we have somewhat limited influence over the decisions made by Esteve or their sublicensees or the resources they devote to the marketing and distribution of Surfaxin products in their licensed territory, and we cannot assure you that they will meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and we may not receive any revenues from it. Also, we cannot assure you that we will be able to enter into marketing and sales agreements on acceptable terms, if at all, for Surfaxin in territories not covered by the Esteve agreement, or for any of our other product candidates.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates from 2004 through 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals or products; and
- manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, there are no approved drugs that are specifically indicated for the prevention and treatment of Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Current therapy consists of general supportive care and mechanical ventilation.

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Exosurf[®] is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. This product, however, does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer. Curosurf[®] is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta[®], marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf[®] in the United States for the treatment of Respiratory Distress Syndrome in premature infants. Although none of the four approved surfactants for Respiratory Distress Syndrome in premature infants is approved for Acute Lung Injury or Acute Respiratory Distress Syndrome in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for these indications that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered precision-engineered surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Respiratory Distress Syndrome in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”) or causing adverse immunological responses in young and older adults.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are

developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

If product liability claims are brought against us, it may result in reduced demand for our products or damages that exceed our insurance coverage.

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to \$10.0 million per occurrence and \$10.0 million in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of September 30, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 16% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic,

political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to our Business”.

Our common stock is listed for quotation on the NASDAQ National Market. During the nine-month period ended September 30, 2004, the price of our common stock has ranged from \$5.75 to \$13.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended September 30, 2004, the average daily trading volume in our common stock was approximately 537,000 shares and the average number of transactions per day was approximately 1,499. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the National Market. If the common stock were no longer listed on the National Market, investors might only be able to trade on the Nasdaq SmallCap Market, in the over-the-counter market in the Pink Sheets[®] (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board[®] of the National Association of Securities Dealers, Inc. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of September 30, 2004, we had 47,021,413 shares of common stock outstanding. In addition, as of September 30, 2004, up to approximately 8,808,949 shares of our common stock were issuable upon exercise of outstanding options and warrants. On December 19, 2003, we filed a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. Since the shelf registration statement was filed, we have sold 2,200,000 shares under the registration statement leaving 4,300,000 shares of our common stock available for us to sell in registered transactions under the shelf registration statement. We have no immediate plans to sell any securities under the shelf registration. However, subject to the effectiveness of the shelf registration statement, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time. Additionally, there are 15,000,000 shares of our common stock that are reserved for issuance under the CEFF arrangement with Kingsbridge. See "Risks Related to our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholders Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Restated Certificate of Incorporation, as amended, allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a shareholders rights agreement which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the shareholders rights agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer. We currently do not hedge interest rate or currency exchange exposure. We classify

highly liquid investments purchased with a maturity of three months or less as “cash equivalents” and commercial paper and fixed income mutual funds as “available for sale securities.” Fixed income securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

The Company’s management, including its CEO and CFO, does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive and financial officers reviewed and evaluated our disclosure controls and procedures (as defined in Rule 13a-15 promulgated under the Securities Exchange Act of 1934) prior to the filing of this Quarterly Report. Based on that evaluation and subject to the limitations noted above, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in timely providing them with material information, as required to be disclosed in the reports we file pursuant to the Exchange Act.

(b) Changes in internal controls

There were no significant changes in our internal controls or other factors that could significantly affect those controls subsequent to the date of our evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In the quarter ended September 30, 2004, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 106,435 shares of our common stock at various exercise prices ranging from \$1.42 to \$8.377 per share. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker-dealers were involved in the sale and no commissions were paid by us.

We have a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, we allowed for periodic discretionary matches of newly issued shares of common stock with the amount of any such match determined as a percentage of each participant's cash contribution. The total match for the quarter ended September 30, 2004 was approximately \$57,000.

During the nine months ended September 30, 2004, certain members of our management, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tendered shares of common stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the nine months ended September 30, 2004, 146,204 shares of our common stock were tendered to us by such parties in lieu of cash at an average price of 12.07 per share. These shares are accounted for as treasury stock. See Part I, Item 1: "Financial Statements, Note 5 – Treasury Stock".

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

- 4.1 Warrant Agreement, dated as of November 3, 2004, by and between QFinance, Inc. and the Company
- 4.2 Amended and Restated Promissory Note, dated as of November 3, 2004, issued to PharmaBio
- 10.1 Agreement, dated as of November 3, 2004, by and among Quintiles, PharmaBio and the Company

- 10.2 Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of November 3, 2004, by and between PharmaBio Development Inc. and the Company
- 10.3 Amended and Restated Security Agreement, dated as of December 10, 2001, amended and restated as of November 3, 2004, by and between PharmaBio Development Inc. and the Company
- 31.1 Section 302 Certification of Chief Executive Officer
- 31.2 Section 302 Certification of Chief Financial Officer
- 32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer

Signatures, and Certifications of the Chief Executive Officer and the Chief Financial Officer of the Company.

Exhibits 31.1, 31.2 and 32.1 to this Quarterly Report on Form 10-Q include Certifications of our Chief Executive Officer and our Chief Financial Officer.

The first two forms of Certification are required by Rule 13a-14 under the Exchange Act in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (the “Section 302 Certifications”). The Section 302 Certifications include references to an evaluation of the effectiveness of the design and operation of our “disclosure controls and procedures” and our “internal controls and procedures for financial reporting”. Item 4 of Part I of this Quarterly Report presents the conclusions of our Chief Executive Officer and our Chief Financial Officer about the effectiveness of such controls based on and as of the date of such evaluation (relating to Item 4 of the Section 302 Certifications), and contain additional information concerning disclosures to our Audit Committee and independent auditors with regard to deficiencies in internal controls and fraud and related matters.

The second form of Certification is being furnished solely pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsection (a) and (b) of section 1350, chapter 63 of title 18, United States Code) and is not being filed as part of this Form 10-Q or as a separate disclosure document. A signed original of such written statement required by Section 906, or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to us and will be retained by us and furnished to the Securities and Exchange Commission or its staff upon request.

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 9, 2004

/s/ Robert J. Capetola
Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: November 9, 2004

/s/ John G. Cooper
John G. Cooper
Executive Vice President and Chief
Financial Officer
(Principal Financial Officer)

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 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.

WARRANT AGREEMENT

This WARRANT AGREEMENT is dated and entered into as of November 3, 2004, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and QFINANCE, INC., a Delaware corporation ("QFinance").

WHEREAS, the Company and PharmaBio Development Inc., an affiliate of QFinance, have entered into the Amended and Restated Loan Agreement dated as of December 10, 2001 and amended and restated as of the date hereof (as amended, the "Loan Agreement"), and other agreements dated as of the date hereof; and

WHEREAS, the Company desires to grant to QFinance the rights set forth in this Warrant Agreement;

NOW, THEREFORE, for 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 QFinance, its designees or assigns (the "Holder") up to Eight Hundred Fifty Thousand (850,000) shares (the "Warrant Shares") of the Company's common stock, par value \$.001 per share ("Common Stock"), at an exercise price equal to Seven Dollars and Nineteen Cents (\$7.19) per share (the "Exercise Price"), and upon the terms and conditions set forth herein. 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. The Holder may exercise this Warrant Agreement at any time commencing on the earlier to occur of the FDA Approval Date (as defined below) and May 2, 2005, 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 substantially in the form attached hereto as Annex A properly completed and executed, at the principal office of the Company on a Business Day (as defined below), and (b) upon payment by (i) 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, (ii) cancellation of an amount of indebtedness of the Company under the Loan Agreement, or (iii) a combination of (i) and (ii), 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. Upon exercise of this Warrant Agreement and payment of the purchase price by the Holder, all Warrant Shares deliverable and issued hereunder will be duly authorized, duly and validly issued and outstanding, fully paid and nonassessable, and free from taxes, liens or charges. "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. "FDA Approval Date" means the earlier of (i) the first date on which the FDA approves an application to market the Product, or (ii) the first date on which the Company receives an "approvable letter" from the FDA with respect to the Product. "FDA" means the United States Food and Drug Administration or its successor. "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 (i) respiratory distress syndrome (RDS), or (ii) meconium aspiration syndrome (MAS).

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 or share exchange are exchanged or converted by virtue of the merger or share exchange into other property, whether in the form of securities, cash, or otherwise, or (iii) a sale, lease, license or other transfer 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, exchange 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, exchange or transfer that a holder of the shares deliverable upon exercise of this Warrant Agreement would have been entitled to receive in such reorganization, merger, consolidation, exchange or transfer if this Warrant Agreement had been exercised immediately

before the record date of (or the date of, if no record date is fixed) such reorganization, merger, consolidation, exchange 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, exchanges 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 4.

(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, reclassification, transfer of assets, consolidation, merger, business combination, dissolution, issuance 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 by the Company under this Section 4 or the other terms of this Warrant Agreement, 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 Section 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. 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 reorganization or recapitalization of the Company, any reclassification of the capital stock of the Company, any consolidation, merger, share exchange or other business combination of the Company with or into another corporation or entity, or any sale, lease, license or other transfer of all or substantially all of the assets of the Company to another corporation or entity; or

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

then, and in each such case, the Company will cause written notice thereof to be delivered to the Holder specifying, as the case may be, (i) 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 (ii) the date on which such reorganization, recapitalization, reclassification, consolidation, merger, share exchange, business combination, transfer, 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, recapitalization, consolidation, merger, share exchange, business combination, transfer, dissolution, liquidation or winding-up. Such notice shall be delivered at least fifteen (15) Business Days prior to the date required to be specified therein pursuant to this Section 6(c).

7. Reservation of Shares; Listing. (a) 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 such 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 capital stock issuable upon exercise of this Warrant Agreement and the conversion of such stock, if applicable. If the number of authorized but unissued shares of capital stock shall not be sufficient to effect the exercise the entire amount of this Warrant Agreement on the Exercise Date or the conversion of such stock, if applicable, then 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 capital stock to such number of shares as shall be sufficient for such purposes.

(b) The Company will at all times use its best efforts to keep the Warrant Shares authorized for listing on the Nasdaq National Market, the Nasdaq SmallCap Market, or any national securities exchange on which its Common Stock is traded.

8. 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.

9. Transfer Restriction. 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 or "blue sky" 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 and the securities laws of each relevant state. Notwithstanding anything in this Warrant Agreement to the contrary, the Holder may pledge the Warrant Agreement and the Warrant Shares in connection with bona fide loan transactions in which the Holder or its affiliate is the borrower, provided that no such pledge shall occur (i) prior to January 1, 2005, without the prior written consent of the Company (which consent shall not be unreasonably withheld), and (ii) upon and after January 1, 2005, knowingly, after reasonable investigation and inquiry, to any person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product or device which directly competes with the Product.

10. Registration Rights.

(a) Required Registration. Not later than December 15, 2004 (the "Filing Date"), the Company shall prepare and file with the Securities and Exchange Commission ("SEC") a registration statement on Form S-3 (except if the Company is not then eligible to use Form S-3, in which case such registration statement shall be on another appropriate form) (the "Registration Statement") covering the resale of all of the Registrable Securities (as defined below) in an offering to be made on a continuous basis pursuant to Rule 415 of the Securities

Act. The Company shall use its commercially reasonable best efforts to cause such registration statement to become effective not later than February 1, 2005 and remain effective for the period specified in Section 10(d) below. Subject to any modifications that are responsive to comments, rules or regulations of the SEC, the Registration Statement will include a Plan of Distribution, which shall be no more restrictive than that included in the Company's registration statement on Form S-3, SEC File No. 333-101666. For purposes of this Agreement, the term "Registrable Securities" means the Warrant Shares, together with any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to any Registrable Securities. Until such time as the Registration Statement is effective, the Company shall not grant any registration rights or other rights to register securities under the Securities Act that are senior to the rights of the Holder under this Section 10(a) or that have the effect of delaying a sale or limiting the number of securities which may be sold by the Holder pursuant to the Registration Statement or otherwise adversely affect the rights of the Holder under this Section 10(a); provided, however, that the foregoing shall not affect any pre-existing rights granted to any persons or entities.

(b) Registration Expenses. The Company shall pay all Registration Expenses (as defined below) in connection with any registration, qualification or compliance hereunder. At any time during the ninety (90) days following the effective date of the Registration Statement, the Company may present to the Holder an accounting of its reasonable Registration Expenses and, within thirty (30) days thereafter, the Holder shall reimburse the Company for such expenses up to an aggregate amount not to exceed Twenty Thousand Dollars (\$20,000). "Registration Expenses" shall mean all expenses incurred by the Company in complying with the registration provisions herein described, including without limitation all registration, qualification, notification and filing fees, printing expenses, fees and disbursements of counsel and accountants for the Company, and blue sky fees and expenses.

(c) Holder Review of Registration Statement. Upon request received by the Company from the Holder within a reasonable time in advance, the Company shall, on or prior to the third trading day prior to the filing of the Registration Statement or any related prospectus or any amendment or supplement thereto, (i) furnish to the Holder copies of all such documents proposed to be filed (including documents incorporated or deemed incorporated by reference to the extent requested by such person) which documents will be subject to the review of the Holder, and (ii) cause its officers and directors, counsel and independent certified public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel to conduct a reasonable investigation within the meaning of the Securities Act.

(d) Certain Company Obligations During Effectiveness of Registration Statement. From the date of effectiveness of the Registration Statement, the Company will use its best efforts to: (i) keep such registration effective until the earlier of (A) such date as all of the Registrable Securities have been resold or (B) such date as all Registrable Securities may be sold pursuant to Rule 144(k) (or any successor rule) (collectively, the "Effectiveness Period"); (ii) promptly prepare and file with the SEC such amendments and supplements to the Registration Statement and the prospectus used in connection with the Registration Statement as may be necessary to comply with the provisions of the Securities Act with respect to the

disposition of all securities covered by the Registration Statement; (iii) furnish such number of prospectuses and other documents incident thereto, including any amendment of or supplement to the prospectus, as the Holder from time to time may reasonably request; (iv) cause the Registrable Securities to be quoted or listed on each stock market or stock exchange on which the Common Stock of the Company is then quoted or listed; (v) provide a transfer agent and registrar for all securities registered pursuant to the Registration Statement and a CUSIP number for all such securities; (vi) avoid the issuance of, or, if issued, promptly notify the Holder and obtain the withdrawal of, any order suspending the effectiveness of a Registration Statement; (vii) promptly notify the Holder of the issuance by the SEC or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (viii) promptly notify the Holder of the occurrence of any event or passage of time that makes the financial statements included in the Registration Statement ineligible for inclusion therein or any statement made in the Registration Statement or prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to the Registration Statement, prospectus or other documents so that, in the case of the Registration Statement or the prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; (ix) unless available on the Internet free of charge, promptly furnish to the Holder, without charge, at least one conformed copy of the Registration Statement and each amendment thereto, including financial statements and schedules, all documents incorporated or deemed to be incorporated therein by reference to the extent requested by such person, and all exhibits to the extent requested by such person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the SEC; and (x) file the documents required of the Company and otherwise use its best efforts to maintain requisite blue sky clearance in North Carolina and such other states of the United States specified in writing by the Holder; provided, however, that the Company shall not be required to qualify to do business in any state in which it is not now so qualified or has not so consented.

(e) Suspension of Use of Prospectus. The Holder hereby acknowledges that there may occasionally be times when the Company must suspend the use of the prospectus forming a part of the Registration Statement until such time as an amendment to the Registration Statement has been filed by the Company and declared effective by the SEC or until the Company has amended or supplemented such prospectus. The Holder hereby covenants that it will not sell any securities pursuant to said prospectus during the period commencing at the time at which the Company gives the Holder notice of the suspension of the use of said prospectus and ending at the time the Company gives the Holder notice that Holder may thereafter effect sales pursuant to said prospectus. Notwithstanding anything herein to the contrary, the Company shall not suspend use of the prospectus forming a part of the Registration Statement by the Holder unless in the good faith opinion of the Company (after consultation with its counsel) or its counsel such suspension is required by the federal securities laws, including without limitation, the rules and regulations promulgated thereunder; provided, however, that in the event that such suspension is required by the need for an amendment or supplement to the Registration Statement or the prospectus forming a part thereof, the Company shall use its best efforts to file

as soon as practicable such required amendments or supplements as shall be necessary for the disposition of the Registrable Securities to recommence.

(f) Holder Information for Registration Statement. As a condition to the inclusion of its Registrable Securities, the Holder shall furnish to the Company such information regarding the Holder and the distribution proposed by the Holder as the Company may reasonably request in order to comply with any applicable law or regulation in connection with any registration, qualification or compliance referred to in this Section 10.

(g) Indemnification and Contribution.

(1) To the extent permitted by applicable law, the Company will indemnify and hold harmless each seller of Registrable Securities that were registered pursuant to the Registration Statement, 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 the 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 10(g)(1) 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 of the Company from all liability in respect of such claim or litigation.

(2) To the extent permitted by applicable law, each seller of Registrable Securities that were registered pursuant to the Registration Statement, 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 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 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 10(g)(2) 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 of such seller 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.

(3) 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 10(g) and shall only relieve it from any liability which it may have to such indemnified party under this Section 10(g) 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 10(g) 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.

(4) 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 10(g) 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 10(g) 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 10(g); 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.

11. Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the SEC that may permit the sale of securities to the public without registration, the Company agrees to use commercially 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 to be filed by the Company under the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and furnish a written report 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 Exchange Act.

12. SEC and Other Information.

So long as this Warrant Agreement is in effect, the Company shall comply with the following covenants:

(a) Upon written request, the Company will provide to the Holder, within three (3) Business Days of receipt of such written request, a copy of any publicly available forms, reports or other documents filed by the Company with the SEC if such documents are not available on the Internet free of charge. If for any reason at any time the Company is not required to file annual, quarterly and other periodic reports with the SEC pursuant to the terms of the Exchange Act, then the Company shall make available at no charge to the Holder financial statements no later than the time they would be filed with the SEC if the Company was required to file such annual, quarterly and other periodic reports.

13. Additional Provisions. (a) The Holder represents, by accepting this Warrant Agreement, that it understands that this Warrant Agreement and any securities obtainable upon exercise of this Warrant Agreement have not been registered for sale under Federal or state securities or “blue sky” laws and are being offered and sold to the Holder pursuant to one or more exemptions from the registration requirements of such securities laws. In the absence of an effective registration of such securities or an exemption therefrom, any certificates for such securities shall bear a legend substantially similar to the legend set forth on the first page of this Warrant Agreement. The Holder understands that it must bear the economic risk of its investment in this Warrant Agreement and any securities obtainable upon exercise of this Warrant Agreement for an indefinite period of time, as this Warrant Agreement and such securities have not been registered under Federal or state securities or blue sky laws and therefore cannot be sold unless subsequently registered under such laws, unless an exemption from such registration is available.

(b) The Holder agrees and acknowledges that this Warrant Agreement, or any portion hereof, and any such securities will not be sold, transferred, assigned, hypothecated or otherwise disposed of unless (i) a registration statement with respect to such transfer is effective under the Securities Act and any applicable state securities or blue sky laws or (ii) such sale or transfer is made pursuant to one or more exemptions from the Securities Act.

(c) The Holder represents that it 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 terms and conditions of this Warrant Agreement or the exercise of this Warrant Agreement and the finance operations and business of the Company and (ii) the opportunity to request such additional information which the Company possesses or can acquire without unreasonable effort or expense. Nothing contained in this Section 11(c) shall alter, amend or change the Holder’s reliance on the representations, covenants or warranties contained herein.

(d) The Holder represents that it did not (i) receive or review any advertisement, article, notice or other communication published in a newspaper or magazine or similar media or broadcast over television or radio, whether closed circuit, or generally available; or (ii) attend any seminar, meeting or investor or other conference whose attendees were, to such Holder’s knowledge, invited by any general solicitation or general advertising.

(e) The Holder represents that it is an “accredited investor” within the meaning of Regulation D promulgated under the Act. Such Holder is acquiring this Warrant Agreement for its own account and not with a present view to, or for sale in connection with, any distribution thereof in violation of the registration requirements of the Act.

(f) The Holder represents that it, either by reason of the Holder’s 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 sophistication, knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment in the Company.

(g) The Holder represents that it has the ability to bear the economic risks of its investment for an indefinite period of time and could afford a complete loss of its investment.

(h) The Holder agrees and acknowledges that the representations and warranties made by the Holder in this Section 13 shall be deemed also to be made at the time of the exercise of this Warrant Agreement.

(i) Nothing in this Section 13 shall affect in any way the Holder's obligations under any agreement to comply with all applicable securities laws upon resale of the Warrant Shares.

14. 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) Assignment. This Warrant Agreement shall be binding upon and inure to the benefit of the Holder and its respective successors and permitted assigns, provided that the Holder shall not assign or transfer any or all of its rights under this Warrant Agreement (i) prior to January 1, 2005, without the prior written consent of the Company (which consent shall not be unreasonably withheld), and (ii) upon and after January 1, 2005, knowingly, after reasonable investigation and inquiry, to any person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product or device which directly competes with the Product. Notwithstanding the foregoing, the Holder may assign any or all of its rights under this Warrant Agreement to an affiliate of the Holder. Any assignment or attempted assignment in violation of this Section 14(b) shall be null and void.

(c) 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.

(d) Warrant Exchangeable for Different Denominations. This Warrant Agreement is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company for new Warrant Agreements of like tenor representing in the aggregate the right to purchase the number of shares which may be purchased hereunder, each of such new Warrant Agreements to represent the right to purchase such number of Warrant Shares as shall be designated by said Holder hereof at the time of such surrender.

(e) Law Governing. This Warrant Agreement will be governed by, and construed and enforced in accordance with, the internal laws of the State of Delaware. 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 Loan Agreement entitled “Internal Review” and “Arbitration” set forth in Sections 8.14 and 8.15 thereof, respectively, after modifying such Sections so that any references to “Loan Documents” or the “Agreement” shall mean this Warrant Agreement and any references to the “Borrower” or “Lender” shall mean the Company or the Holder, respectively.

(f) 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.

(g) 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:

Dickstein Shapiro Morin & Oshinsky LLP

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

(ii) If to QFinance, then to:

QFinance, Inc.
c/o PharmaBio Development Inc.
4709 Creekstone Drive
Riverbirch 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 14(g).

(h) 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.

[Rest of page intentionally left blank; signatures 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/ John G. Cooper
Name: John G. Cooper
Title: Executive Vice President and Chief
Financial Officer

QFINANCE, INC.

By: /s/ David Andrews
Name: David Andrews
Title: Vice President and Assistant Secretary

ANNEX A

EXERCISE FORM

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

DISCOVERY LABORATORIES, INC.

SUBSCRIPTION

The undersigned, _____, pursuant to the provisions of the foregoing Warrant Agreement, hereby elects to exercise such Warrant Agreement by agreeing to subscribe for and purchase _____ shares (the "Warrant Shares") of Common Stock, par value \$.001 per share, of Discovery Laboratories, Inc. (the "Company"), and hereby makes payment of \$_____ by certified or official bank check in payment of the exercise price therefor.

As a condition to this subscription, the undersigned hereby represents and warrants to the Company that the representations and warranties of Section 13 of the Warrant Agreement are true and correct as of the date hereof as if they had been made on such date with respect to the Warrant Shares. The undersigned further acknowledges that the sale, transfer, assignment or hypothecation of the Warrant Shares to be issued upon exercise of the Warrant Agreement is subject to the terms and conditions contained in Sections 4, 9 and 13 of the Warrant Agreement.

Dated: _____

Signature: _____

Address: _____

ASSIGNMENT

FOR VALUE RECEIVED _____ hereby sells, assigns and transfers unto _____ the foregoing Warrant Agreement and all rights evidenced thereby, and does irrevocably constitute and appoint _____, attorney, to transfer said Warrant Agreement on the books of Discovery Laboratories, Inc. (the "Company"). As a condition to this assignment, the Holder acknowledges that its assignee must deliver a written instrument to the Company that the representations and warranties of Section 13 of the Warrant Agreement are true and correct as of the date hereof as if they had been made by such assignee on such date.

Dated: _____

Signature: _____

Address: _____

PARTIAL ASSIGNMENT

FOR VALUE RECEIVED _____ hereby assigns and transfers unto _____ the right to purchase _____ shares of the Common Stock, par value \$.001 per share, of Discovery Laboratories, Inc. (the "Company"), as set forth in the foregoing Warrant Agreement, and a proportionate part of said Warrant Agreement and the rights evidenced thereby, and does irrevocably constitute and appoint _____, attorney, to transfer that part of said Warrant Agreement on the books of the Company. As a condition to this assignment, the Holder acknowledges that its assignee must deliver a written instrument to the Company that the representations and warranties of Section 13 of the Warrant Agreement are true and correct as of the date hereof as if they had been made by such assignee on such date.

Dated: _____

Signature: _____

Address: _____

**AMENDED AND RESTATED
PROMISSORY NOTE**

\$8,500,000

November 3, 2004

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. For the avoidance of doubt, Borrower agrees that in the event that the aggregate unpaid principal amount of all Advances exceeds \$8,500,000 then, upon the written request of Lender, Borrower shall immediately pay to Lender in cash the amount of such excess. 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.

This Note is made and dated as of December 10, 2001 and amended and restated as of the date set forth above. 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 Note is the Note referenced in the Amended and Restated Loan Agreement between Borrower and Lender dated as of December 10, 2001 and amended and restated as of the date hereof (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 the Amended and Restated Security Agreement between Borrower and Lender dated as of the date hereof.

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 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.

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 8.14 and 8.15 thereof, respectively.

DISCOVERY LABORATORIES, INC.

By: /s/ John G. Cooper

Name: John G. Cooper

Title: Executive Vice President and Chief
Financial Officer

ADVANCES AND PAYMENTS OF PRINCIPAL

<u>Date</u>	<u>Amount of Advance</u>	<u>Amount of Principal Paid or Prepaid</u>	<u>Unpaid Principal Balance</u>	<u>Notation Made By</u>
10-1-04	\$5,432,618	\$0	\$5,432,618	

AGREEMENT

This AGREEMENT (this "Agreement") is dated and made as of November 3, 2004, by and between Discovery Laboratories, Inc., a Delaware corporation ("Discovery"), Quintiles Transnational Corp., a North Carolina corporation ("Quintiles"), and PharmaBio Development Inc., a North Carolina corporation ("PharmaBio").

WHEREAS, Discovery and Quintiles previously entered into the Commercialization Agreement dated as of December 10, 2001 (the "Commercialization Agreement"); and

WHEREAS, Discovery and PharmaBio previously entered into the following documents, each dated as of December 10, 2001: the Common Stock and Warrant Purchase Agreement (the "Stock Purchase Agreement"), the Investment and Commission Agreement (the "Investment Agreement"), and the Loan Agreement (the "Loan Agreement"); and

WHEREAS, Discovery previously delivered to PharmaBio the Promissory Note dated as of December 10, 2001 (the "Original Note");

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:

1. Contemporaneously with the execution and delivery of this Agreement, (a) Discovery and PharmaBio are executing and delivering an Amended and Restated Loan Agreement (the "Amended Loan Agreement"), (b) Discovery is executing and delivering to PharmaBio an Amended and Restated Promissory Note in connection with the Amended Loan Agreement (the "Amended Note"), (c) Discovery and PharmaBio are executing and delivering an Amended and Restated Security Agreement in connection with the Amended Loan Agreement, and (d) Discovery and QFinance, Inc. ("QFinance"), an affiliate of Quintiles and PharmaBio, are executing and delivering a Warrant Agreement providing for the right of QFinance to purchase up to 850,000 shares of Discovery's common stock, par value \$0.001 per share, in consideration of this Agreement and the foregoing.

2. (a) The Commercialization Agreement is hereby terminated, subject to Section 12.8 of the Commercialization Agreement. Notwithstanding the provisions of Section 12.8, Sections 7.5, 7.6, 9.2 and 12.6, and Article 11, of the Commercialization Agreement shall not survive such termination. Further, Section 14.2 of the Commercialization Agreement which survives the termination is hereby amended in its entirety as follows:

"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 Chief Executive Officers of Discovery and Quintiles. 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.”

(b) The parties acknowledge and agree that the parties have resolved the amount of all invoices and charges with respect to the Commercialization Agreement and the Loan Agreement, including without limitation the matters described in the letter from Discovery to Quintiles dated August 4, 2004, and the letter from Discovery to Quintiles dated August 9, 2004.

3. The Investment Agreement is hereby terminated, subject to Section 10.2 of the Investment Agreement. Notwithstanding the provisions of Section 10.2, Section 7 of the Investment Agreement shall not survive such termination.

4. Article VI (entitled Subscription Right) and Article VIII (entitled Additional Agreements) of the Stock Purchase Agreement are hereby terminated.

5. The Original Note is hereby superseded and replaced by the Amended Note. PharmaBio hereby agrees that it shall, promptly following execution of the Amended Note, surrender the Original Note to Discovery at the following address: 350 South Main Street, Suite 307, Doylestown, PA 18901-4874, Attn: President.

6. (a) Discovery hereby grants to Quintiles, for a period of three (3) years from the date of this Agreement (the “Term”), the status of a preferred provider for Discovery on the terms and conditions set forth in this Section 6. If at any time during the Term, Discovery determines to engage a third party to perform Outsourced Services (as defined below) for or on behalf of Discovery within the United States, then Discovery will not engage a third party to perform such services without having afforded to Quintiles a bona fide opportunity to make an offer to Discovery for the provision of such Outsourced Services. Accordingly, Discovery shall notify Quintiles of such opportunity to provide Outsourced Services and shall provide to Quintiles information and materials relating to such opportunity, on a basis that is comparable to the notice, information and materials provided by Discovery to third parties with respect to the applicable Outsourced Services. In order to facilitate this preferred provider relationship, Quintiles and Discovery will each designate and maintain a contact person for such preferred provider relationship and will inform the other party of such person (or as such person may change from time to time). “Outsourced Services” shall mean and include any pre-clinical, clinical, or sales and marketing services that fall within the areas of recognized expertise of Quintiles. For purposes of this Section, “Quintiles” shall mean and include Quintiles and its affiliates and “Discovery” shall mean Discovery and its affiliates.

(b) Notwithstanding the foregoing:

(i) Discovery is not under any obligation to negotiate in good faith or to use any quantum of effort, including but not limited to “best efforts,” to reach an agreement with respect to the provision of Outsourced Services by Quintiles;

(ii) Discovery is free to negotiate with any one or more third parties at the same time it is negotiating with Quintiles and, except as explicitly herein provided, to solicit interest from any available sources;

(iii) Discovery may engage any party that is currently performing Outsourced Services on behalf of Discovery to continue to perform such Outsourced Services without Discovery being obligated to offer to Quintiles an opportunity to make an offer to Discovery in connection with the provision of such Outsourced Services;

(iv) Discovery may engage any party to perform any Outsourced Services without Discovery being obligated to offer to Quintiles an opportunity to make an offer to Discovery in connection with the provision of such Outsourced Service in the event that Discovery, in its sole discretion, has determined to outsource such Outsourced Service, or is engaged in substantive negotiations with such party, prior to the date hereof;

(v) Discovery may, or may engage any of its affiliates to, perform any Outsourced Services without Discovery offering to Quintiles a bona fide opportunity to make an offer to Discovery in connection with the provision of any Outsourced Services;

(vi) Discovery is not obligated to offer to Quintiles a bona fide opportunity to make an offer to Discovery in connection with the provision of any Outsourced Services if the amount to be paid by Discovery for such Outsourced Services does not exceed \$75,000; and

(vii) This Section 6 shall be null and void and of no force or effect for so long as PharmaBio shall be in material breach of the Amended Loan Agreement, or if the Amended Loan Agreement is terminated or expired.

7. The Medical Science Liaison agreement between Discovery and Innovex (an affiliate of Quintiles and PharmaBio), Work Order No. 4149 Discovery Surfaxin Pre-Launch MSL Program, dated November 1, 2003, is and shall remain in full force and effect in accordance with its terms, and is not affected by this Agreement.

8. Until the earlier of (i) such time that PharmaBio or its Affiliates (as defined in the Amended Loan Agreement) (the "PharmaBio Parties") beneficially own less than one percent of the issued and outstanding shares of Common Stock of Discovery, and (ii) the completion of Discovery's annual meeting of shareholders for the calendar year 2006, at each annual meeting of the shareholders of Discovery or in connection with any other meeting or action by written consent in lieu of a meeting of the shareholders of Discovery, the PharmaBio Parties shall vote or act with respect to all shares of Common Stock beneficially owned by them (w) in favor of all persons nominated by the then current Board of Directors of Discovery for election to the Board of Directors of Discovery, (x) in favor of any employee stock option plan, any similar equity incentive plan and any amendments and supplements to the foregoing which have been recommended by the Board of Directors, and (y) in favor of any increase or other change to the authorized amount of shares of capital stock of Discovery which have been recommended by the Board of Directors, and for any charter amendments required to be filed in connection therewith; provided, that, for the avoidance of doubt, clauses (x) and (y) shall not apply to any matter that is

related to the matters which are subject to the Transaction Agreements (as defined in the Amended Loan Agreement), to any Change of Control (as defined in the Amended Loan Agreement), or to any matter which PharmaBio determines in good faith may materially adversely affect Discovery's ability to satisfy its obligations under the Transaction Documents. The voting agreement contained in this Section 8 is irrevocable to the extent permitted by applicable law and is coupled with an interest. For purposes of this Section 8, beneficial ownership shall be determined in accordance with Rule 13d-3 under the Securities Act of 1933, and PharmaBio and its affiliates shall be deemed to beneficially own all shares of Common Stock that may be directly or indirectly issuable to them upon exercise or conversion of any security of Discovery even if such security is not then exercisable or convertible.

9. (a) No amendment or waiver of any provision of this Agreement, nor consent to any departure by Discovery therefrom, shall in any event be effective unless the same shall be in writing and signed by Discovery, Quintiles and PharmaBio, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

(b) 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 Discovery: Discovery Laboratories, Inc.
350 South Main Street
Suite 307
Doylestown, PA 18901-4874
Attn: President
Facsimile: (215) 340-3940

with a copy to: Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas
New York, NY 10036-2714
Attn: Ira L. Kotel
Facsimile: (212) 997-9880

If to Quintiles
or PharmaBio: 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 Wachovia Capitol Center
Raleigh, NC 27601
Attn: Christopher B. Capel
Facsimile: (919) 821-6800

(c) No failure on the part of Quintiles or PharmaBio 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.

(d) In the event that any dispute among the parties 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.

(e) This Agreement shall be binding upon and inure to the benefit of Discovery, Quintiles and PharmaBio and their respective successors and assigns; provided, that neither Discovery, Quintiles nor PharmaBio 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 consent shall be null and void.

(f) 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.

(g) This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersede all prior oral or written agreements and understandings relating to the subject matter hereof.

(h) 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.

(i) 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.

(j) 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).

(k) Neither Quintiles, PharmaBio nor Discovery, nor any of each 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.

(l) 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.

(m) 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 Chief Executive Officers of Discovery and Quintiles. 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.

(n) (1) If the parties are unable to resolve any Dispute under Section 9(m), 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(n). 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.

(2) 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 fourteen (14) days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within fourteen (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.

(3) 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(n) in order to assert such counterclaim(s).

(4) 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 9(n).

(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 9(n), 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.

(5) Except as provided in the last sentence of Section 9(n)(1), the provisions of this Section 9(n) 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(n) shall pay the costs of the other party, including, without limitation, reasonable attorney’s fees and defense costs.

10. In consideration of the foregoing provisions of this Agreement, Quintiles and Discovery each agrees that it will refrain from making derogatory or disparaging statements or communications to third parties regarding the other party or its affiliates with respect to the

Commercialization Agreement, the Stock Purchase Agreement, the Investment Agreement, or the Loan Agreement; the transactions contemplated thereby; or the performance of the parties or their affiliates thereunder; provided, however, that this Section shall not restrict Discovery from giving truthful, required testimony or taking any other action required by applicable law and this Section shall only apply to senior management of Discovery.

[Rest of page intentionally left blank; signatures on following page]

[Signature page to Agreement]

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

DISCOVERY LABORATORIES, INC.

By: /s/ John G. Cooper
Name: John G. Cooper
Title: Executive Vice President and Chief
Financial Officer

QUINTILES TRANSNATIONAL CORP.

By: /s/ Ronald Wooten
Name: Ronald Wooten
Title: Executive Vice President

PHARMABIO DEVELOPMENT INC.

By: /s/ William O. Robb
Name: William O. Robb
Title: Vice President

**AMENDED AND RESTATED
LOAN AGREEMENT**

THIS LOAN AGREEMENT (this "Agreement") is dated as of December 10, 2001, and amended and restated as of November 3, 2004 (the "Restatement Date") by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender").

WHEREAS, Borrower and Lender entered into the Loan Agreement (the "Original Loan Agreement") dated as of December 10, 2001 (the "Original Date");

WHEREAS, Borrower and Lender wish to amend and restate the Original Loan Agreement in its entirety as set forth in 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 amend and restate the Original Loan Agreement in its entirety and 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, prior to the earlier to occur of either May 15, 2005 or the Product Launch Date (the "Expiry Date"), to make advances (each an "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) (the "Commitment") in lawful money of the United States of America in immediately available funds.

(b) Prior to the Expiry Date, 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 set forth in this Agreement.

(c) Notwithstanding anything to the contrary in this Agreement, upon the Expiry Date, (i) the Commitment will be automatically reduced to the aggregate principal amount of the Advances outstanding as of that time, (ii) no additional Advances will be made under this Agreement, and (iii) the Commitment may not be used on a revolving basis.

(d) 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, then, upon the written request of Lender, Borrower shall immediately pay to Lender in cash the amount of such excess.

(e) Each Advance shall be a principal amount of a loan, evidenced by the Note referred to below.

2.02 Use of Proceeds. The Advances shall 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 \$250,000.

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 dated as of the Original Date and amended and restated as of the Restatement Date. 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 December 31, 2006, unless any such amount becomes 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 of the amount of the prepayment and (ii) each prepayment shall not be less than \$250,000.

(b) 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) eight percent (8.0%) or (ii) two percent (2.0%) 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.

(c) 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.

(d) The outstanding principal amount of an Advance or any accrued interest amounts thereon that are not paid when due shall accrue interest on a daily basis at the lesser of (i) three percent (3%) 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.

(e) All payments of principal and interest 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 this Agreement. The obligation of Lender to execute and deliver this Agreement to Borrower is subject to the conditions precedent that Lender shall have received from Borrower each of the following documents on the Restatement Date:

(a) The Note duly executed by Borrower;

(b) A Security Agreement in a form acceptable to the parties (the "Security Agreement"), and the related financing statement in a form acceptable to the parties, in each case duly executed by Borrower;

(c) A Warrant Agreement in a form acceptable to the parties and dated as of the Restatement Date (the “Warrant”), duly executed by Borrower;

(d) An agreement in a form and substance acceptable to the parties (the “Supplemental Agreement”), duly executed by Borrower, providing for the termination of certain contracts, a preferred provider arrangement, and certain other matters;

(e) Copies of resolutions of the Board of Directors of Borrower approving this Agreement, the Note, the Security Agreement and any other documents required or necessary to consummate the transactions contemplated in this Agreement (collectively, the “Loan Documents”), the Warrant, and the Supplemental Agreement (together with the Loan Documents, collectively, the “Transaction Documents”), certified by an appropriate officer of Borrower;

(f) A certificate of the appropriate officers of Borrower certifying (i) that the representations and warranties contained in Article IV are true and correct in all material respects, (ii) that Borrower has performed, satisfied and complied with, in all material respects, 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 (iii) that no event has occurred and is continuing, which constitutes an Event of Default (as defined in Section 7.01 hereof) or would constitute an Event of Default but for the requirement that notice be given or time elapse or both; and

(g) A certificate of good standing (or comparable document) regarding Borrower from the State of Delaware.

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 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; and

(d) All principal amount of Advances or accrued interest under this Agreement, which are due and payable at the time of such Advance, shall have been paid in full.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF BORROWER

Borrower represents, warrants and covenants to Lender, as of the Restatement Date, as follows:

4.01 Corporate Status. Borrower is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and Borrower is qualified to do business as a foreign corporation in each jurisdiction in which qualification is required, except where failure to so qualify will not violate any provision of the organizational documents of Borrower, and would not have a material adverse effect on the financial condition, properties, business or results of operations of Borrower (a “Material Adverse Effect”). Except for Acute Therapeutics, Inc., a wholly owned subsidiary of Borrower that is presently inactive (“ATI”), Borrower does not own or control, directly or indirectly, any interest in any other corporation, partnership, limited liability company, association, or other business entity. Except as set forth in the SEC Reports, Borrower is not a participant in any joint venture, partnership, or similar arrangement. Borrower has all requisite corporate power and authority to carry on its business as now conducted.

4.02 Issuance, Sale and Delivery of the Securities. The Warrant is, and the Warrant Shares, when issued and paid for pursuant to the terms of the Warrant, will be, duly and validly authorized, duly 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 Warrant is not, and the issuance of the Warrant Shares by Borrower (hereinafter such securities are sometimes collectively referred to as the “Securities”) will not be, subject to any preemptive or other similar rights. No further approval or authority of the stockholders or the Board of Directors of Borrower will be required for the issuance and sale of the Securities to be sold by Borrower as contemplated herein.

4.03 Due Execution, Delivery and Performance of the Agreements. Borrower has full legal right, corporate power and authority to enter into the Transaction Documents and to perform the transactions contemplated under the Transaction Documents. The Transaction Documents have been duly authorized, executed and delivered by Borrower. Except as set forth herein, the making and performance of the Transaction Documents by Borrower and the consummation of the transactions contemplated therein will not result in the creation of any lien, charge, security interest or encumbrance upon any assets of Borrower 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 Borrower is a party or by which Borrower or its properties may be bound or affected and in each case which would have a Material Adverse Effect or violate 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 Borrower or any of its properties. Except for any required notifications or qualifications under the federal and state securities or “blue sky” laws and regulations with respect to the issuance of the Warrant, the Warrant Shares and the Note, 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 the Transaction Documents or the consummation of the transactions contemplated thereby. The Transaction Documents constitute valid and binding obligations of Borrower, 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.

4.04 Financial Statements and Reports. Unless available on the Internet free of charge, Borrower has made available to Lender true and complete copies of 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 Borrower included in the SEC Reports have been prepared in accordance with United States generally accepted accounting principles ("GAAP") 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 Borrower 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. Borrower 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.

4.05 No Defaults. Except as to defaults, violations and breaches which individually or in the aggregate would not have a Material Adverse Effect, Borrower 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 Borrower as defined in such documents, except such defaults which individually or in the aggregate would not have a Material Adverse Effect.

4.06 Contracts.

(a) The contracts and agreements of Borrower described in the SEC Reports, including without limitation Borrower's licenses and options for licenses, are in full force and effect as of the Restatement Date and Borrower is not, nor to Borrower'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, except such contracts or agreements as may have expired in accordance with their terms. All such contracts and agreements constitute valid and binding obligations of Borrower, 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 4.06(a), Borrower makes the following representations and warranties in this Section 4.06(b) regarding (i) the Sublicense Agreement dated October 28, 1996 (the "Sublicense") among Johnson & Johnson and Ortho Pharmaceutical Corporation, as licensors (collectively, "Licensor"), and ATI, as licensee, and (ii) the Research Funding and Option Agreement dated March 1, 2000 (the "Research Agreement") between the Scripps Research Institute and Borrower:

(1) Borrower is the successor to ATI under the Sublicense.

(2) The Sublicense is in full force and effect, and Borrower is not, nor to Borrower'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 Borrower'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 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.

(3) To Borrower'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.

(4) Borrower 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 Borrower.

(5) The Research Agreement is not a material contract of the Borrower with respect to its financial condition, results of operations, prospects, or products.

4.07 No Actions. There are no legal or governmental actions, suits, proceedings, arbitrations or investigations pending or, to Borrower's knowledge, threatened, to which Borrower is or may be a party or of which property owned, leased or licensed by Borrower 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 effect on the transactions contemplated by this Agreement or result in a material adverse change in the financial condition, properties, business, or results of operations of Borrower (a "Material Adverse Change"); and no labor disturbance by the employees of Borrower exists or is imminent, to Borrower's knowledge, which might reasonably be expected to have a Material Adverse Effect. Borrower 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.

4.08 Properties. Borrower 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 Borrower. Borrower holds its leased properties under valid and binding leases. Borrower owns, leases or licenses all such properties necessary for the conduct of its business (as described in the SEC Reports).

4.09 No Material Change. Except as disclosed in the SEC Reports, since January 1, 2004: (i) Borrower 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 Borrower; (ii) Borrower 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) Borrower has not paid or declared any dividends or other distributions with respect to its capital stock and Borrower 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 Borrower, other than options issued pursuant to employee equity incentive plans or purchase plans approved by Borrower's Board of Directors, or indebtedness material to Borrower; and (v) except for the operating losses and negative cash flow Borrower has continued to incur, there has not been any Material Adverse Change.

4.10 Intellectual Property. (a) Borrower owns or has obtained valid rights to use the inventions, patent applications, patents, trademarks (both registered and unregistered), tradenames, and, to Borrower's knowledge after reasonable investigation and inquiry, copyrights and trade secrets, necessary for the conduct of Borrower's business (as described in the SEC Reports) (collectively, the "Intellectual Property"); and (b) to Borrower'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, Borrower for the product indications described in the SEC Reports that would preclude Borrower 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 Borrower; (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 Borrower; (iii) there is no pending or threatened action, suit, proceeding or claim by others challenging the rights of Borrower in or to any Intellectual Property owned, licensed or optioned by Borrower; (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 Borrower; (v) there is no pending or threatened action, suit, proceeding or claim by others that Borrower infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary right of others; and (vi) Borrower 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 Borrower 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.

4.11 Compliance. Borrower has been and is in compliance with, in all material respects, 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 FFDCFA, environmental issues, and taxes and other governmental charges.

4.12 Taxes. Borrower 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 Borrower has no knowledge of a tax deficiency which has been or might be asserted or threatened against it.

4.13 Insurance. Borrower maintains insurance with sound and reputable insurance companies of the types and in the amounts that Borrower reasonably believes is adequate for its business, including, but not limited to, insurance covering all real and personal property owned or leased by Borrower against all risks customarily insured against by similarly situated companies, all of which insurance is in full force and effect.

4.14 No Undisclosed Liabilities. Neither Borrower nor any of its subsidiaries has any liabilities, obligations, claims or losses (whether liquidated or unliquidated, secured or unsecured, absolute, accrued, contingent or otherwise) that would be required to be disclosed on a balance sheet of Borrower or any subsidiary (including the notes thereto) in accordance with GAAP and are not disclosed in the SEC Reports other than those incurred in the ordinary course of Borrower's or its subsidiaries' respective businesses since December 31, 2003, and which, individually or in the aggregate, do not or would not have a Material Adverse Effect.

4.15 No Undisclosed Events or Circumstances. To Borrower's knowledge, no event or circumstance has occurred or exists with respect to Borrower or its subsidiaries or their respective businesses, properties, operations or financial condition, which, under applicable law, rule or regulation, requires public disclosure or announcement by Borrower but which has not been so publicly announced or disclosed and which, individually or in the aggregate, do not or would not have a Material Adverse Effect.

4.16 Disclosure. To Borrower's knowledge, as of their respective dates, the Transaction Documents (as any of them may have been amended or supplemented after the Restatement Date) contain no untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made herein or therein, in the light of the circumstances under which they were made herein or therein, not misleading.

4.17 Material Non-Public Information. As of the Restatement Date, except for this Agreement and the transactions contemplated hereby, neither Borrower nor its agents have disclosed to Lender any material non-public information that, according to applicable law, rule or regulation, should have been disclosed publicly by Borrower prior to the Restatement Date but which has not been so disclosed.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF LENDER

Lender represents and warrants to Borrower, as of the Restatement Date as follows:

5.01 Corporate Status. Lender is a corporation duly organized, validly existing and in good standing under the laws of the State of North Carolina. Lender has all requisite corporate power and authority to carry on its business as now conducted.

5.02 Due Execution, Delivery and Performance of Agreement. Lender and its Affiliates have full legal right, corporate power and authority to enter into the Transaction Documents and to perform the transactions contemplated thereunder. This Agreement has been duly authorized, executed and delivered by Lender. This Agreement constitutes the valid and binding obligation of Lender enforceable in accordance with its terms.

5.03 Investment. Lender is acquiring the Note, the Warrant and the Warrant Shares for Lender'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. Lender acknowledges receiving and reviewing the SEC Reports. Lender has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of Borrower concerning the business affairs and financial condition of Borrower and (ii) the opportunity to request such additional information which Borrower possesses or can acquire without unreasonable effort or expense and has had access to and has acquired sufficient information about Borrower to reach an informed and knowledgeable decision to acquire the Securities to be purchased hereunder. Lender, 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 Borrower or any Affiliate, finder or selling agent of Borrower, 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 is able to bear the risks of an investment in the Securities. Lender 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. Lender is not a "broker" or a "dealer" as defined in the Exchange Act and is not an "affiliate" of Borrower as defined in Rule 405 promulgated under the Securities Act.

5.04 Accredited Investor. Lender is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act.

5.05 Note, the Warrant and the Warrant Shares Not Registered. Lender understands that the Note, the Warrant and the Warrant Shares 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. Lender 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 one or more of the Note, the Warrant and the Warrant Shares, 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 the Warrant and (ii) neither the Note, the Warrant 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. Lender understands that unless and until the Warrant and the Warrant Shares have been registered for resale by Borrower or Lender in compliance with applicable securities laws, the certificates evidencing the Warrant and the Warrant Shares will be imprinted with a legend (in accordance with Section 5.06) that prohibits the transfer of the Warrant 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 Borrower, an opinion of counsel reasonably satisfactory to Borrower is obtained to the effect that the transaction is not required to be registered or is so exempt. Notwithstanding anything in this Agreement to the contrary, Lender may pledge the Note, the Warrant, and the Warrant Shares in connection with bona fide loan transactions in which Lender or its Affiliate is the borrower, provided that no such pledge shall occur (i) prior to January 1, 2005, without the prior written consent of Borrower (which consent shall not be unreasonably withheld), and (ii) upon and after January 1, 2005, knowingly, after reasonable investigation and inquiry, to any person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product or device which directly competes with the Product.

5.06 Legend. To the extent applicable, each certificate evidencing the Warrant 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 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.”

ARTICLE VI COVENANTS OF BORROWER

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

6.01 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.

6.02 Transfers of Assets. Borrower shall not, and shall not permit any of its subsidiaries to, 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, (b) any material assets, properties or rights relating to the Product, or (c) any of its assets or properties except in the ordinary course of business and so long as such action is not likely to have a Material Adverse Effect or a material adverse effect on Lender's rights hereunder.

6.03 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 each of the following forms of Debt, individually and not in the aggregate:

- (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 \$5,000,000 in the aggregate, (which shall not include any Debt described in clauses (c) and (d));
- (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 \$10,000,000 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, unless such Junior Debt is described in clauses (a) through (c) above, 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.

6.04 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 \$10,000,000, (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, unless such Junior Liens are described in clauses (a) through (c) above, 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.

6.05 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 Restatement Date.

6.06 Exchange Act Registration. Borrower will cause the Common Stock to continue to be registered under Section 12(g) of 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.

6.07 SEC and Other Information.

(a) Upon written request, Borrower will provide to Lender, within three (3) Business Days of receipt of such written request, a copy of any publicly available forms, reports or other documents filed by Borrower with the SEC if such documents are not available on the Internet free of charge. If for any reason at any time Borrower is not required to file annual, quarterly and other periodic reports with the SEC pursuant to the terms of the Exchange Act, then Borrower shall make available at no charge to Lender financial statements no later than the time they would be filed with the SEC if Borrower was required to file such annual, quarterly and other periodic reports. Any audited consolidated financial statements and unaudited interim financial statements prepared pursuant to the preceding sentence shall be prepared in accordance with GAAP applied on a consistent basis (except as may be indicated therein or in the notes thereto) during the periods involved, and shall fairly present in all material respects the financial position of Borrower as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited interim financial statements, to normal year-end audit adjustments).

(b) Borrower will permit officers and designated representatives of Lender, at reasonable times and intervals during normal business hours, and upon reasonable prior notice, to visit and inspect, under guidance of officers of Borrower, any of the properties of Borrower, and to examine the books of record and account of Borrower and discuss the affairs, finances and accounts of Borrower with, and be advised as to the same by, Borrower's officers; provided, that Lender shall, and shall cause its Affiliates and representatives to, treat all nonpublic information made available to it in strict confidence and disclose such information 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. Lender shall be responsible for any disclosure of such information by its Affiliates, subcontractors and employees.

6.08 Notice of Certain Events. Promptly, and in any event within five (5) Business Days after an executive officer of Borrower 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.

6.09 Compliance with Certain Agreements. Borrower shall perform and fulfill all of its obligations under the Sublicense as necessary to maintain Borrower's rights in such agreement 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 Sublicense proposing or threatening to terminate any such agreement.

6.10 Insurance. Borrower shall maintain in full force and effect insurance with sound and reputable insurance companies of the types and in the amounts that Borrower reasonably believes is adequate for its business, including, but not limited to, insurance covering all real and personal property owned or leased by Borrower against all risks customarily insured against by similarly situated companies.

ARTICLE VII EVENTS OF DEFAULT

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

(a) Borrower shall fail to pay any principal of, or interest on, any Advance or the Note when the same becomes due and payable and four (4) Business Days have elapsed following receipt of written 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 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 6.02, 6.03 or 6.04) and such failure to perform or observe such term, covenant or agreement has a Material Adverse Effect 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 6.02, 6.03 or 6.04, except, in the case of Section 6.04, if an Event of Default is based on a tax lien, judgment lien or materialman's lien, such lien 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 \$250,000 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 GAAP) at least equal to the net worth of Borrower immediately prior to the consummation of the applicable transaction and such entity agrees in a written instrument enforceable by Lender 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 to Lender 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) Borrower shall fail to perform or observe any term, covenant or agreement under the Security Agreement in any material respect, or the Security Agreement or any material provision thereof shall cease to be in full force and effect;

(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) which, taken as a whole, materially adversely affects 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 Borrower or its Affiliates of any debt or other obligations permitted by this Agreement;

- (l) the Common Stock shall not be listed or quoted on an Eligible Market;
- (m) The Sublicense shall have been terminated or expired, or cease to be in full force and effect for the benefit of Borrower;
- (n) Borrower shall withdraw, terminate, or abandon the NDA to market the Product;
- (o) The Product Launch Date shall not have occurred within one hundred eighty (180) days after the FDA Approval Date; or
- (p) Following the Product Launch Date, Borrower shall withdraw the Product from the market.

7.02 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 Lender's 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 7.01(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 VIII MISCELLANEOUS

8.01 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.

8.02 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
Doylestown, PA 18901-4874
Attn: President
Facsimile: (215) 340-3940

with a copy to: Dickstein Shapiro Morin & Oshinsky LLP
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 Wachovia Capitol Center
Raleigh, NC 27601
Attn: Christopher B. Capel
Facsimile: (919) 821-6800

8.03 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.

8.04 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.

8.05 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of Borrower and Lender and their respective successors and permitted assigns, provided that (a) Borrower shall not assign or transfer any or all of its rights or obligations under any of the Loan Documents, and (b) Lender shall not assign or transfer any or all of its rights or obligations under any of the Loan Documents (i) prior to the Expiry Date, without the prior written consent of Borrower (which consent shall not be unreasonably withheld), and (ii) upon

and after the Expiry Date, knowingly, after reasonable investigation and inquiry, to any person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product or device which directly competes with the Product. Notwithstanding the foregoing, Lender may assign any or all of its rights or obligations under any of the Loan Documents to an Affiliate of Lender. Any assignment or attempted assignment in violation of this Section 8.05 shall be null and void.

8.06 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.

8.07 Entire Agreement. This Agreement and the other Transaction Documents 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 Documents shall affect, or be used to interpret, change or restrict, the express terms and provisions of the Transaction Documents. If any provision contained in this Agreement shall be deemed to conflict with any provision of any of the other Transaction Documents, then the provision contained in this Agreement shall be controlling.

8.08 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 the Transaction Documents.

8.09 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.

8.10 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).

8.11 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 the Loan Documents, 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.

8.12 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.

8.13 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.

8.14 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 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.

8.15 Arbitration.

(a) If the parties are unable to resolve any Dispute under Section 8.14, 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 8.15. 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 fourteen (14) days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within fourteen (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 8.15 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 8.15.

(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 8.15, 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 8.15(a), the provisions of this Section 8.15 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 8.15 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 Amended and Restated Loan Agreement]

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

BORROWER:

DISCOVERY LABORATORIES, INC.

By: /s/ John G. Cooper
Name: John G. Cooper
Title: Executive Vice President and Chief
Financial Officer

LENDER:

PHARMABIO DEVELOPMENT INC.

By: /s/ William O. Robb
Name: William O. Robb
Title: Vice President

EXHIBIT A DEFINITIONS

“Advances” shall have the meaning set forth in Section 2.01(a).

“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; (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.

“Commitment” shall have the meaning set forth in Section 2.01(a).

“Common Stock” shall mean the common stock, par value \$0.001 per share, of Borrower.

“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 GAAP, 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.

“Eligible Market” means any national securities exchange, the Nasdaq National Market or the Nasdaq SmallCap Market.

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

“Expiry Date” shall have the meaning set forth in Section 2.01(a).

“FDA” shall mean the United States Food and Drug Administration or its successor.

“FDA Approval Date” shall mean the first date on which the FDA approves an application to market the Product.

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

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

“Material Adverse Change” shall have the meaning set forth in Section 4.07.

“Material Adverse Effect” shall have the meaning set forth in Section 4.01.

“NDA” shall mean a “new drug application” as such term is used under the FFDCA.

“Note” shall have the meaning set forth in Section 2.04.

“Prime Rate” shall mean the rate which Wachovia 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 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 (i) respiratory distress syndrome (RDS), or (ii) meconium aspiration syndrome (MAS).

“Product Launch Date” shall mean the first date on which the Product is shipped in the United States for commercial sale.

“SEC” shall mean the United States Securities and Exchange Commission.

“SEC Reports” shall mean Borrower’s most recently filed Annual Report on Form 10-K and the Proxy Statement filed in connection with Borrower’s most recent annual meeting of stockholders and all Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed by Borrower after January 1, 2004.

“Securities Act” shall mean the Securities Act of 1933, as amended.

“Security Agreement” shall have the meaning set forth in Section 3.01(b).

“Sublicense” shall have the meaning set forth in Section 4.06(b).

“Warrant” shall have the meaning set forth in Section 3.01(c).

“Warrant Shares” shall mean the shares issuable by Borrower upon the exercise of the Warrant.

EXHIBIT B
FORM OF NOTE

AMENDED AND RESTATED SECURITY AGREEMENT

THIS SECURITY AGREEMENT (this "Agreement") is dated as of December 10, 2001, and amended and restated as of November 3, 2004 by and between DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), and PHARMABIO DEVELOPMENT INC., a North Carolina corporation ("Lender").

WITNESSETH:

WHEREAS, Borrower and Lender previously entered into that certain Security Agreement dated as of December 10, 2001 (the "Original Agreement");

WHEREAS, Borrower and Lender wish to amend and restate the Original Agreement in its entirety as set forth in this Agreement;

WHEREAS, Borrower and Lender are parties to the Amended and Restated Loan Agreement dated as of December 10, 2001, and amended and restated as of the date hereof (as amended, modified or supplemented from time to time, the "Loan Agreement"), 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, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the parties hereby amend and restate the Original Agreement in its entirety and hereby agree as follows:

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

"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.

"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 License Agreement 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 License Agreement; (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 the License Agreement 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 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 the Contracts.

“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 (as successor to 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 (i) respiratory distress syndrome (RDS), or (ii) meconium aspiration syndrome (MAS).

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

“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.

“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 or in the Loan Agreement.

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 or licensee 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 6.02 and 6.04 of the Loan Agreement are hereby incorporated herein by reference.

5. Other Financing Statements. Borrower represents, warrants and covenants to and with Lender that, except for the financing statement filed by Borrower in connection with the Original Agreement 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. Without limiting the foregoing, Lender is hereby authorized to file one or more financing statements, continuation statements, or other documents for the purpose of perfecting or continuing the security interest granted by Borrower, without the signature of Borrower, and naming Borrower as debtor and Lender as secured party; provided, that Lender shall provide copies of all such documents to Borrower.

(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 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 in full force and effect insurance with sound and reputable insurance companies of the types and in the amounts that Borrower reasonably believes is adequate for its business, including, but not limited to, insurance covering all real and personal property owned or leased by Borrower against all risks customarily insured against by similarly situated companies.

(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 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 fifteen (15) Business Days, Borrower will not change its name, change its state of incorporation, dissolve, merge, or consolidate with any other person; provided, that Borrower shall not be required to make any disclosure to Lender hereunder that constitutes material non-public information. 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; provided, that Borrower shall not be required to make any disclosure to Lender hereunder that constitutes material non-public information.

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 Wachovia 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:

Dickstein Shapiro Morin & Oshinsky, LLP
1177 Avenue of the Americas
New York, NY 10036-2714
Attention: Ira L. Kotel
Facsimile: (212) 997-9880

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 Note 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 permitted assigns, provided that (i) Borrower may not assign or transfer any or all of its rights or obligations under the Security Documents, and (ii) Lender may not assign or transfer any or all of its rights or obligations under the Security Documents except in connection with an assignment or transfer of

the Loan Agreement pursuant to the terms of the Loan Agreement. Any assignment or attempted assignment in violation of this Section 16 shall be null and void.

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 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 fourteen (14) days after receiving notice of commencement of arbitration, or if the two arbitrators fail to choose a third arbitrator within fourteen (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:

(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 23.

(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 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.

(e) 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.

[Rest of page intentionally left blank; signatures on following page]

[Signature page to Amended and Restated Security Agreement]

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/ John G. Cooper
Name: John G. Cooper
Title: Executive Vice President and Chief
Financial Officer

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/ William O. Robb
Name: William O. Robb
Title: Vice President

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Robert J. Capetola, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - c) disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2004

/s/ Robert J. Capetola
Robert J. Capetola, Ph.D.
President and Chief Executive Officer

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, John G. Cooper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - c) disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2004

/s/ John G. Cooper
John G. Cooper
Executive Vice President and
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Discovery Laboratories, Inc. (the "Company"), for the period ended September 30, 2004, as filed with the Securities and Exchange Commission (the "Commission") on the date hereof (the "Report"), each of the undersigned, in his capacity as an officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Commission or its staff upon request.

Date: November 9, 2004

Name: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.

Title: President, and
Chief Executive Officer

Name: /s/ John G. Cooper

Name: John G. Cooper

Title: Executive Vice President, and
Chief Financial Officer