UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

|X| QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2002

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 small business issuer as specified in its charter)

Delaware	94-3171943
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
350 South Main Street, Suite 307 Doylestown, Pennsylvania	18901
(Address of principal executive offices)	(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 |X| No |_|

As of November 6, 2002, 32,849,683 shares of Common Stock, par value $.001 per share, were outstanding.

Transitional Small Business Disclosure Format: |_| Yes |X| No

DISCOVERY LABORATORIES, INC., AND SUBSIDIARY
(a development stage company)

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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 1996

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 the Company to fund its 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; possible changes in our financial condition; the progress of our research and development (including the risk that our lead product candidate, Surfaxin(R), will not prove to be safe or useful for the treatment of certain indications); 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 and the failure of collaborators to perform under their agreements with us; the results of clinical trials being conducted by us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional cost and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the other risks and certainties detailed in Item 2: "Management's Discussion and Analysis" 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.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Condensed Consolidated Balance Sheets

	Sept 30, 2002 (Unaudited)	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,402,000	$ 3,758,000
Available-for-sale marketable securities	7,572,000	12,938,000
Note receivable - current	2,000	2,000
Prepaid expenses and other current assets	753,000	1,580,000
Total current assets	11,729,000	18,278,000
Property and equipment, net of accumulated depreciation	1,122,000	822,000
Note receivable	195,000	197,000
Other assets	122,000	768,000
Total assets	$ 13,168,000	$ 20,065,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,000,000	$ 1,750,000
Capitalized lease - current	114,000	44,000
Total current liabilities	2,114,000	1,794,000
Deferred revenue	1,641,000	615,000
Credit facility with corporate partner	1,257,000	--
Capitalized lease	69,000	33,000
Total liabilities	5,081,000	2,442,000
Stockholders' Equity:		
Common stock, $.001 par value; 60,000,000 authorized; 26,452,166 and 25,546,293 shares issued and outstanding at Sept 30, 2002 and December 31, 2001, respectively	26,000	26,000
Additional paid-in capital	75,528,000	73,163,000
Unearned portion of compensatory stock options	(95,000)	(264,000)
Deficit accumulated during the development stage	(67,321,000)	(55,135,000)
Treasury stock (at cost; 38,243 shares of common stock)	(239,000)	(239,000)
Accumulated other comprehensive income	188,000	72,000
Total stockholders' equity	8,087,000	17,623,000
	$ 13,168,000	$ 20,065,000

See notes to condensed consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,		May 18, 1993 (inception) through Sept 30,
	2002	2001	2002	2001	2002
Revenues:					
Research and development collaborative contracts	$ 368,000	$ 197,000	$ 1,388,000	$ 915,000	$ 3,446,000
Expenses:					
Write-off of acquired in-process research and development and supplies	--	--	--	--	13,508,000
Research and development	3,475,000	1,921,000	9,801,000	5,732,000	38,171,000
General and administrative	1,633,000	733,000	4,303,000	2,772,000	22,270,000
Total expenses	5,108,000	2,654,000	14,104,000	8,504,000	73,949,000
Operating loss	(4,740,000)	(2,457,000)	(12,716,000)	(7,589,000)	(70,503,000)
Other income and expense:					
Interest income, dividends, realized gains, and other income	256,000	(61,000)	607,000	658,000	3,959,000
Minority interest in net loss of subsidiary	--	--	--	--	26,000
Interest expense	(45,000)	(1,000)	(77,000)	(3,000)	(121,000)
Net loss	$ (4,529,000)	$ (2,519,000)	$(12,186,000)	$ (6,934,000)	$(66,639,000)
Net loss per common share - basic and diluted	$ (0.17)	$ (0.12)	$ (0.46)	$ (0.33)	
Weighted average number of common shares outstanding -	26,440,880	21,188,000	26,222,925	21,045,000	

See notes to condensed consolidated financial statements

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended Sept 30,		May 18, 1993 (inception) through September 30,
	2002	2001	2002
Cash flows from operating activities:			
Net loss	$(12,186,000)	$(6,934,000)	$(66,639,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Write-off of licenses	--	--	683,000
Depreciation and amortization	209,000	135,000	753,000
Compensatory stock options	169,000	329,000	3,343,000
Expenses paid using treasury stock and common stock	26,000	35,000	230,000
Loss on sale of property	--	--	4,000
Changes in:			
Prepaid expenses, inventory and other current assets	827,000	(1,000)	408,000
Accounts payable and accrued expenses	250,000	(1,546,000)	1,867,000
Other assets	1,000	(18,000)	(20,000)
Proceeds from research and development collaborative agreements	1,833,000	--	3,474,000
Amortization of deferred revenue	(807,000)	(593,000)	(2,388,000)
Expenses paid on behalf of company	--	--	18,000
Employee stock compensation	--	--	42,000
Reduction of research and development supplies	--	--	(161,000)
Net cash used in operating activities	(9,678,000)	(8,593,000)	(44,878,000)
Cash flows from investing activities:			
Purchase of property and equipment	(332,000)	(109,000)	(2,083,000)
Proceeds from sale of property and equipment	--	--	575,000
Loan to related party	--	(200,000)	(200,000)
Related party loan payments received	2,000	--	3,000
Acquisition of licenses	--	--	(711,000)
Purchase of marketable securities	(5,481,000)	(5,583,000)	(49,416,000)
Proceeds from sale or maturity of marketable securities	10,963,000	9,379,000	42,437,000
Net cash payments on merger	--	--	(1,670,000)
Net cash provided by (used in) investing activities	5,152,000	3,487,000	(11,065,000)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	2,956,000	1,000,000	58,300,000
Proceeds from credit facility	1,257,000	--	1,257,000
Purchase of treasury stock	--	(26,000)	(121,000)
Principal payments under capital lease obligation	(43,000)	(13,000)	(91,000)
Net cash provided by financing activities	4,170,000	961,000	59,345,000
Net (decrease) increase in cash and cash equivalents	(356,000)	(4,145,000)	3,402,000
Cash and cash equivalents - beginning of period	3,758,000	7,281,000	--
Cash and cash equivalents - end of period	$ 3,402,000	$ 3,136,000	$ 3,402,000
Supplementary disclosure of cash flows information:			
Interest Paid:	$ (37,000)	$ 3,000	$ 7,000
Noncash transactions:			
Class H warrants issued/revalued	$ (617,000)	$ --	$ 151,000
Accrued dividends on Series C preferred stock	--	--	682,000
Series C preferred stock dividends paid using common stock	--	--	204,000
Preferred Stock issued for inventory	--	--	575,000
Equipment acquired through capitalized lease	149,000	--	274,000
Unrealized gain (loss) on marketable securities	116,000	199,000	188,000

Notes to Condensed Consolidated Financial Statements (unaudited)

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

The Company

Discovery Laboratories, Inc. ("we" or the "Company"), is a development stage specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products. Surfactants are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen.

The Company's humanized surfactant technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. These severe respiratory disorders generally are associated with a lack of functional surfactant. The Company's lead product, Surfaxin(R), is an engineered humanized surfactant and is currently in two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants (RDS), a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants (MAS), and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults (ARDS).

The Company is also performing research and development of aerosolized formulations of its humanized surfactant technology to treat respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract.

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 nine-month period ended September 30, 2002, are not necessarily indicative of the results that may be expected for the year ended December 31, 2002. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2001.

The Company is a development stage company and has incurred substantial losses since inception. To date, the Company has funded its operations primarily through the issuance of equity. The Company expects to continue to expend substantial amounts for continued product research, development, and initial commercialization activities for the foreseeable future. Management's plans with respect to funding these development and commercialization activities are to use its secured revolving credit facility with Quintiles Transnational Corp., secure additional capital through the issuance of equity, if possible, and to secure collaborative arrangements that will provide available cash funding for operations. Continuation of the Company is dependent on its ability to obtain additional financing and, ultimately, on its ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that the Company's efforts ultimately will be successful.

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

Certain prior year balances have been reclassified to conform with the current presentation. The reclassification had no effect on net income.

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 and the conversion of convertible securities are not included in the calculation of the net loss per share as their effect would be antidilutive.

NOTE 3 - COMPREHENSIVE LOSS

Total comprehensive loss was approximately $4,424,000 and $12,070,000 for the three and nine months ended September 30, 2002, and approximately $2,095,000 and $6,735,000 for the three and nine months ended September 30, 2001, respectively.

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

Overview

We are a specialty pharmaceutical company applying our technology in humanized lung surfactants to develop potential novel respiratory therapies and pulmonary drug delivery products. Surfaxin, our lead product, is currently in two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults. We are also developing aerosolized formulations of our humanized surfactant to treat respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract.

We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp. to commercialize Surfaxin for Respiratory Distress Syndrome and Meconium Aspiration Syndrome in the United States. We expanded our relationship with Laboratorios del Dr. Esteve, S.A., by entering into a strategic alliance with Esteve to commercialize Surfaxin in Europe, Central and South America, and Mexico. In the non-critical care, ambulatory markets, we plan to establish strategic alliances for the development and commercialization of our products.

Since our inception, we have incurred significant losses and, as of September 30, 2002, had a deficit accumulated during the development stage of approximately $66.6 million (including historical results of predecessor companies). Most of our expenditures to date have been for research and development activities and general and administrative expenses. Research and development expenses represent costs incurred for 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 salaries and related expenses, rents and general corporate activities.

On November 5, 2002, we raised approximately $12.8 million in gross proceeds in a private offering of units consisting of an aggregate of approximately 6.4 million shares of common stock and warrants to purchase an aggregate of approximately 2.9 million shares of common stock. We discuss this financing further in "Liquidity and Capital Resources," below.

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, initial commercialization, and general and administrative activities.

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

(i) significantly increase our research, development and regulatory activities. It is anticipated that the primary focus of our research and development activities will be the several clinical trials for Surfaxin indications and related regulatory filings. In the fall of 2001, we initiated two pivotal, landmark multinational Phase 3 trials for Respiratory Distress Syndrome in premature infants: a 1,500 patient trial and a 500 patient supporting trial. The majority of our development resources are focused on these trials and we currently anticipate completing the trials, announcing data and filing a New Drug Application in the second quarter of 2003. 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. In July 2002, we completed the dose escalation safety and tolerability part of the study and are currently enrolling patients in the final part of the trial. We currently expect data from the Acute Respiratory Distress Syndrome trial to be available in the first quarter of 2003. For Meconium Aspiration Syndrome in full-term infants, we currently are conducting a Phase 3 clinical trial of up to 200 patients in the United States. Enrollment is ongoing but has been slower than expected and completion is currently anticipated for late 2003. Given our belief in the importance of the pivotal Phase 3 trial for Respiratory Distress Syndrome in premature infants to our present development

plan, resources have been and may continue to be reallocated from other programs to the Respiratory Distress Syndrome program, as needed.

The research and development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the risks discussed below in "Risks Related to Our Business-The clinical trial and regulatory approval process for our products will be expensive and time consuming, and the outcome is uncertain."

(ii) conduct research and development of aerosolized formulations of our humanized surfactant in order to develop new products intended to treat respiratory conditions such as asthma, COPD, and Acute Lung Injury/Acute Respiratory Distress Syndrome and as a novel pulmonary drug delivery vehicle to deliver drugs via the respiratory tract. See the risks discussed below in "Risks Related to Our Business-The clinical trial and regulatory approval process for our products will be expensive and time consuming, and the outcome is uncertain."

(iii) invest in additional manufacturing capability in anticipation of optimizing the production process for Surfaxin and to allow scale up of the manufacturing process to meet our clinical and commercial 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.

(v) invest in marketing and commercialization management infrastructure to manage the strategic relationships with our collaborative partners for the launch of Surfaxin, if approved, and the execution of our "Discovery/Surfaxin" worldwide marketing strategy.

On December 10, 2001, we entered into a collaboration arrangement with Quintiles, and its affiliate, PharmaBio Development Inc., to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. Quintiles will hire and train a dedicated United States sales force that will be branded in the market as ours. Quintiles made a financial commitment to us that included a $3 million equity investment, a secured, revolving credit facility of up to $8.5 to $10 million to fund Surfaxin pre-launch activities and up to $70 million in post-launch funding to cover the first seven years of U.S. sales and marketing costs. In return, Quintiles will receive a commission on net sales of Surfaxin over a ten-year period. We may also receive milestone payments from PharmaBio that would be used to offset amounts owed under the credit facility. The Quintiles arrangement allows us to retain product ownership and have sales and marketing expertise in place for the commercialization of Surfaxin in the U.S., if approved. Additionally, the arrangement allows for the specialty sales force to become ours at the end of the seven-year term, with an option to acquire it sooner.

In March 2002, we expanded our existing alliance with Esteve to develop, market and sell Surfaxin throughout Europe, Central and South America, and Mexico. In connection with this new Esteve collaboration, Esteve purchased $4 million of common stock (at a 50% premium over the average closing price for the 30 days prior to the closing date) and paid us a non-refundable licensing fee of $500,000. Esteve agreed to provide certain commercialization services for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. We have agreed to an exclusive supply agreement which 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 has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for Acute Lung Injury/Acute Respiratory Distress Syndrome indications. Esteve also agreed to make certain milestone payments to us upon the attainment of European marketing regulatory approval of Surfaxin. The license fees (including the premium paid for common stock) has been accounted for as deferred revenue and will be recognized as revenue using a straight line method through the anticipated date of FDA approval for the first Surfaxin neonatal indication.

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, 2002, we have yet to generate any revenues from product sales, and have 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 suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies. See the risks discussed below in "Risks Related to Our Business-If we cannot raise additional capital, we may need to discontinue our research and development activities. In addition, any additional financing could result in equity dilution."

Through September 30, 2002, we had not generated taxable income. At December 31, 2001, net operating losses available to offset future taxable income for Federal tax purposes were approximately $47.5 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, as of December 31, 2001, we had a research and development tax credit carryforward of $846,000. 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, 2002 were $4,529,000 ($0.17 per common share) and $12,186,000 ($0.46 per common share), respectively. Net loss for the three and nine months ended September 30, 2001 were $2,519,000 ($0.12 per common share) and $6,934,000 ($0.33 per common share), respectively. Included in the net loss for the three and nine months ended September 30, 2002 were non-cash charges of $857,000 and $1,257,000 for pre-launch marketing activities for Surfaxin for which funding is provided by a secured revolving credit facility pursuant to the Company's collaboration arrangement with Quintiles Transnational Corp., $848,000 and $827,000 for net changes in prepaid balances, and $7,000 and $353,000 for non-cash compensation charges, respectively.

Revenues from research and development collaborative contracts for the three and nine months ended September 30, 2002 were $368,000 and $1,388,000, respectively. Revenues from research and development collaborative contracts for the three and nine months ended September 30, 2001 were $197,000 and $915,000, respectively. Such revenues are related to research and development funding associated with our strategic alliance with Esteve, our Small Business Innovative Research "SBIR" grant to develop Surfaxin for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults and our Orphan Products Development grant to develop Surfaxin for Meconium Aspiration Syndrome in full-term infants.

Research and development expenses for the three and nine months ended September 30, 2002 were $3,475,000 and $9,801,000, respectively. Research and development expenses for the three and nine months ended September 30, 2001 were $1,921,000 and $5,732,000, respectively. This increase primarily reflects clinical trial costs incurred for the Company's lead product, Surfaxin, currently in three Phase 3 trials and one Phase 2 trial, and research and development activities related to our development of aerosolized formulations of our humanized surfactant to treat respiratory conditions and as a pulmonary drug delivery vehicle.

General and administrative expenses for the three and nine months ended September 30, 2002 were $1,645,000 and $4,315,000, respectively. General and administrative expenses for the three and nine months ended September 30, 2001 were $733,000 and $2,772,000, respectively. General and administrative expenses consist primarily of the costs of executive management, financial and accounting, business and commercial development, legal, facility and other administrative costs. Included in general and administrative costs for the first three quarters of 2002 is approximately $1,257,000 for pre-launch commercialization activities (market research and analysis) for Surfaxin conducted in connection with a collaboration arrangement with Quintiles (for which funding is provided by the secured revolving credit facility with PharmaBio discussed below in "Liquidity and Capital Resources"); and a non-cash compensation charge of approximately $353,000 related primarily to options granted to non-employee directors under the Automatic Option Grant Program of the Company's Amended and Restated 1998 Stock Option Plan and to modifications of the terms of certain options previously granted under such Automatic Option Grant Program and held by three departing members of the Board of the Directors of the Company. Such modifications extend the exercisability of such options to their respective stated expiration dates, notwithstanding their original terms.

Interest income for the three and nine months ended September 30, 2002 was $256,000 and $607,000, respectively. Interest income (loss) for the three and nine months ended September 30, 2001 was ($61,000) and $658,000, respectively. Interest income increased during the three months ended September 30, 2002 as compared to the same period of 2001 due to $131,000 of realized gains this period compared to ($232,000) of realized losses in the same period of 2001. Interest income decreased during the nine months ended September

30, 2002 as compared to the same period of 2001 due to declines in interest rates and the average balance of marketable securities.

Liquidity and Capital Resources

As of September 30, 2002, we had working capital of approximately $9.6 million as compared to the working capital of approximately $13.5 million we had as of June 30, 2002 and approximately $16.5 million we had as of December 31, 2001. The decrease in working capital is due to funds used in our clinical trial and research and development activities offset by funds received in connection with the expansion, in March 2002, of our existing alliance with Esteve and the use of the PharmaBio credit facility.

On November 5, 2002, we received approximately $11.9 million in net proceeds in a private financing. In the financing, 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 are first exercisable beginning February 5, 2003, and have a five-year term expiring November 5, 2007. We anticipate using the net proceeds from the financing for working capital and for other general corporate purposes, primarily the continuing research and development of our products. We believe our current working capital is sufficient to meet our planned research and development activities into the second 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.

In December 2001, we entered into a secured revolving credit facility of up to $8.5 million to $10 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. In the third quarter of 2002, the first tranch became available and upon completion of the November 2002 financing, the second tranch is now available. The total funds available under the credit facility is approximately $5.7 million, of which $1,257,000 was outstanding at September 30, 2002. 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. To the extent the credit facility availability is increased to greater than $8.5 million, for each $1 million increase, the amount of shares of common stock issuable pursuant to the Class H warrants shall be increased by approximately 38,000 shares.

Interest on amounts advanced under the credit facility will be payable quarterly in arrears. We may repay principal amounts owed by us under the credit facility from proceeds of milestone payments to be paid to us by PharmaBio upon the achievement of certain corporate milestones. As of September 30, 2002, $1,257,000 was outstanding under the credit facility. We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles. As of September 30, 2002, the outstanding balance under the credit facility was used to fund pre-launch marketing costs incurred in the first three quarters of 2002.

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, the Company's working capital has been provided from the proceeds of private financings:

Pursuant to the collaboration arrangement we entered into 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 aggregate proceeds of $4.5 million.

Pursuant to the collaboration arrangement we entered into with Quintiles and PharmaBio on December 10, 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. The Class G warrants have a ten-year term.

On October 1, 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 have a five-year term.

On April 27, 2001, we received approximately $1 million in gross proceeds in a private offering of 296,560 shares of common stock at a per share price equal to $3.37.

In March 2000, we received approximately $17,500,000 in net proceeds from the sale of 37.74 units from a private placement offering. Each unit consisted of 76,923 shares of common stock and Class E warrants to purchase an additional 15,385 shares of common stock for $7.38 per share. The Class E warrants issued in the offering aggregate approximately 581,000 shares and are exercisable through March 2005.

In October 1999, in connection with our strategic alliance with Esteve, we issued to Esteve in a private placement 317,164 shares of common stock at a purchase price of $2.68 per share.

In July 1999, we raised approximately $2,231,000 in net proceeds in a private placement offering of an aggregate of 2,024,792 shares of common stock and 2,024,792 Class D warrants to purchase common stock. All of the Class D warrants have been exercised.

During March and April 1999, we raised $1.0 million in a private placement offering of 826,447 shares of common stock and 569,026 Class C warrants to purchase common stock at an exercise price of $2.15 per share. The Class C warrants are exercisable through April 2006.

We will require substantial additional funding to conduct our business, including our expanded research and product development activities. Based on our current operating plan, we believe that our currently available resources will be adequate to satisfy our capital needs into the second quarter of 2004. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. We have not entered into any additional arrangements to obtain any additional financing. The sale of additional equity and debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we fail to enter into collaborative ventures or to receive additional funding, we may have to reduce significantly the scope of or discontinue our planned research, development and commercialization activities, which could significantly harm our financial condition and operating results. Furthermore, we could cease to qualify for listing of our common stock on the NASDAQ SmallCap 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."

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 development stage 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 development stage company. Therefore, you must evaluate us in light of the uncertainties and complexities present in a development stage biotechnology company. We 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 these products. 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, 2002, we have incurred a deficit accumulated during the development stage of approximately $66.6 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.

If we cannot raise additional capital, we may need to discontinue our research and development activities. In addition, any additional financing could result in equity dilution.

We may need substantial additional funding to conduct our research and product development activities. Based on our current operating plan, we believe that our currently available resources will be adequate to satisfy our capital needs into the second quarter of 2003. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. If our operations do not become profitable before we exhaust our resources, 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 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.

However, we have not entered into arrangements to obtain any additional financing, except for the credit facility with PharmaBio Development Inc., a subsidiary of Quintiles. 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 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. Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap 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."

The clinical trial and regulatory approval process for our products will be 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 its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices (GMPs) during testing and manufacturing. The process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, the trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of clinical studies necessary for approval. In addition, conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of our clinical trials and the costs of conducting the clinical trials.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture, and sufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, the nature of the protocol, the proximity of the patients to the trial sites and the eligibility criteria for the clinical trials. 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 2004, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997, and the

FDA has awarded us an Orphan Products Development Grant to support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome. 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 shorten the waiting period between the time the New Drug Application is filed and the FDA's review of such application for 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. 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. 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.

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. On March 6, 2002, we expanded our relationship with Laboratorios Del Dr. Esteve, S.A., by entering into a collaboration arrangement with Esteve for Surfaxin covering all of Europe, Central America and South America, and Mexico. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for the commercialization of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

On December 10, 2001, we entered into an exclusive collaboration arrangement in the United States with Quintiles, and its affiliate, PharmaBio, to commercialize, sell and market Surfaxin in the United States for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. As part of our collaboration with Quintiles, Quintiles will build a sales force solely dedicated to the sale of Surfaxin upon the approval of a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio is obligated to provide us with certain financial assistance in connection with the commercialization of Surfaxin, including, but not limited to, a secured, revolving credit facility for at least $8.5 million which may be increased to $10 million. A failure by us to repay amounts outstanding under the credit facility would have a material adverse effect on us. To obtain the benefits of such financing, we are obligated to meet certain development and performance milestones. The failure by us to meet the milestones, our failure to meet other terms and conditions of the financing leading to PharmaBio's termination thereof or the failure of PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

If Esteve, Quintiles or we breach or terminate the agreements that make up such collaboration arrangements or Esteve or Quintiles otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective 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 and/or Quintiles have agreed to assist in commercializing. 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-Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

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, or 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, Inc., and 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 2019. 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 arrangements 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, and the Charlotte-Mecklenberg Hospital Authority. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. 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 this 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.

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 for our products. We have validated only a single clinical manufacturing facility for our drug substance. We will also rely on outside manufacturers for production of our products after marketing approval. We may also enter into arrangements with other manufacturers for the manufacture of materials for use in clinical testing and after marketing approval.

Our outside manufacturers may not perform as they have agreed or may not 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 to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. 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 or manufacturing department 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 good manufacturing practices (GMPs) 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 GMP requirements necessary to continue manufacturing our drug substance. If our third-party foreign or domestic suppliers or manufacturers of our products or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products.

Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales.

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe, Central America and South America, and Mexico. See "Risks Related to Our Business-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." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles' and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, in a timely manner, it will adversely affect sales of our products.

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 in 2003 and 2004. 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 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 are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Curosurf(TM) 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. Exosurf(TM) 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. Survanta(TM), marketed by the Ross division of Abbot Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant

protein B. Forrest Laboratories, Inc., markets its calf lung surfactant, Infasurf(TM) 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 the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered humanized 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 $10,000,000 per occurrence and $10,000,000 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. In addition, significant uncertainty exists as to the reimbursement status of newly approved health care products. Our products may not be considered cost effective. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the research and development of our products.

The United States and other countries continue to propose and pass legislation designed to reduce the cost of healthcare. Accordingly, legislation and regulations affecting the pricing of our products may change before the products are approved for marketing to the public. Adoption of new legislation and regulations could further limit reimbursement for our products. If third party payors fail to provide adequate coverage and reimbursement rates for our products, the market acceptance of the products may be adversely affected. In that case, our business and financial condition will suffer.

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, 2002, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 29% 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 the 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 U.S. 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 these "Management's Discussion and Analysis-Risks Related to Our Business."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the three-month period ended September 30, 2002, the price of our common stock has ranged from $1.97 to $0.90. For the nine-month period ended September 30, 2002, the price of our common stock has ranged from $4.19 to $0.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the three-month period ending September 30, 2002, the average daily trading volume in our common stock was 40,427 shares and the average number of transactions per day was approximately 44. For the nine-month period ending September 30, 2002, the average daily trading volume in our common stock was 46,633 shares and the average number of transactions per day was approximately 49. 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 SmallCap Market. If our common stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets(R) (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board(R) 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, 2002, we had 26,452,166 shares of common stock outstanding. In addition, as of September 30, 2002, up to approximately 8,138,600 shares of our common stock were issuable on exercise of outstanding options and warrants.

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 and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation 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 Certificate of Incorporation 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.

Item 3. 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

Evaluation of the Company's Controls and Procedures. Within the 90 days prior to the date of this Quarterly Report on Form 10-Q, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures (Disclosure Controls), and its internal controls and procedures for financial reporting (Internal Controls). This evaluation (the Controls Evaluation) was done under the supervision and with the participation of management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Rules adopted by the Securities and Exchange Commission (SEC) require that the Company present in this section of the Quarterly Report the conclusions of the CEO and the CFO about the effectiveness of the Company's Disclosure Controls and Internal Controls based on and as of the date of the Controls Evaluation.

Disclosure Controls and Internal Controls. Disclosure Controls are procedures that are designed with the objective of ensuring that information required to be disclosed in the Company's reports filed under the Securities Exchange Act of 1934 (Exchange Act), such as this Quarterly Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Internal Controls are procedures which are designed with the objective of providing reasonable assurance that the Company's (1) transactions are properly authorized; (2) assets are safeguarded against unauthorized or improper

use; and (3) transactions are properly recorded and reported, all to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

Limitations on the Effectiveness of Controls. The Company's management, including, without limitation, the CEO and CFO, does not expect that our Disclosure Controls or our Internal Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of the Company's control system reflects the fact that there are resource constraints, and the benefits of such controls were 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. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon 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, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Scope of the Controls Evaluation. The CEO/CFO evaluation of our Disclosure Controls and our Internal Controls included a review of the overall system's objectives and design, the controls' implementation by the Company and the effect of the controls on the information generated for use in this Quarterly Report. In the course of the Controls Evaluation, the Company sought to identify data errors, controls problems or acts of fraud and to confirm that appropriate corrective action, including process improvements, were being undertaken. This type of evaluation will be done on a periodic basis so that the conclusions concerning controls effectiveness can be reported in the Company's Quarterly Reports on Form 10-Q and Annual Report on Form 10-K. Our Internal Controls are also evaluated on an ongoing basis by the personnel in our finance and accounting organization and by our independent auditors in connection with their audit and review activities. The overall goals of these various evaluation activities are to monitor our Disclosure Controls and our Internal Controls and to make modifications as necessary; our intent in this regard is that the Disclosure Controls and the Internal Controls will be maintained as dynamic systems that change (including with improvements and corrections) as conditions warrant.

Among other matters, we sought in our evaluation to determine whether there were any significant deficiencies or material weaknesses in the Company's Internal Controls, or whether the Company had identified any acts of fraud involving personnel who have a significant role in the Company's Internal Controls. This information was important both for the Controls Evaluation generally and because items 5 and 6 in the Section 302 Certifications as defined below require that the CEO and CFO disclose that information to the Company's Audit Committee of its Board of Directors and to its independent auditors and to report on related matters in this section of the Quarterly Report. In the professional auditing literature, significant deficiencies are referred to as reportable conditions; these are control issues that could have a significant adverse effect on the ability to record, process, summarize and report financial data in the financial statements. A material weakness is defined in the auditing literature as a particularly serious reportable condition where the internal control does not reduce to a relatively low level the risk that misstatements caused by error or fraud may occur in amounts that would be material in relation to the financial statements and not be detected within a timely period by employees in the normal course of performing their assigned functions. The Company also sought to deal with other controls matters in the Controls Evaluation, and in each case if a problem was identified, The Company considered what revision, improvement and/or correction to make in accord with our on-going procedures.

In accord with SEC requirements, the CEO and CFO note that, since the date of the Controls Evaluation to the date of this Quarterly Report, there have been no significant changes in Internal Controls or in other factors that could significantly affect Internal Controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

CEO and CFO Certifications. Appearing immediately following the Signatures section of this Quarterly Report there are two separate forms of Certifications of the CEO and the CFO. The first form of Certification is required in accord with Section 302 of the Sarbanes-Oxley Act of 2002 (the Section 302 Certification). This section of the Quarterly Report which you are currently reading is the information concerning the Controls Evaluation referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Conclusions. Based upon the Controls Evaluation, the Company's CEO and CFO have concluded that, subject to the limitations noted above, the Disclosure Controls are effective to ensure that material information relating to the Company is made known to management, including the CEO and CFO, particularly during the period when our periodic reports are being prepared, and that our Internal Controls are effective to provide reasonable assurance that our financial statements are fairly presented in conformity with generally accepted accounting principles.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 2. CHANGE IN SECURITIES.

In November 2002, the Company sold to certain institutional and accredited investors shares of Common Stock and a newly created class of warrants of the Company (the "Class I Warrants") for an aggregate purchase price of approximately $12.8 million (the "November 2002 Financing"). After payment of fees and associated expenses, the Company intends to use the net proceeds of approximately $11.9 million for working capital and general corporate purposes, including further development of Surfaxin and its platform technology, based on humanized lung surfactants. The issuance of the securities received by investors in the November 2002 Financing was deemed to be exempt from registration under the Act in reliance on Section 4(2) thereof and Regulation D promulgated thereunder because such issuance did not involve a public offering. Investors in the November 2002 Financing represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities certificates issued in such transactions. The investors in the November 2002 Financing had adequate access to information about the Company. Moreover, such investors represented to the Company, and the Company believed, that they were experienced in financial matters.

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 AND REPORTS ON FORM 8-K.

(a) Exhibits:

99.1 Section 302 Certification of Chief Executive Officer

99.2 Section 302 Certification of Chief Financial Officer

99.3 Section 906 Certification of Chief Executive Officer

99.4 Section 906 Certification of Chief Financial Officer

(b) Reports on Form 8-K:

None.

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

The following pages include the Signatures page for this Quarterly Report on Form 10-Q, and two separate Certifications of the Chief Executive Officer and the Chief Financial Officer of the Company.

The first form of Certification is required by Rule 13a-14 under the Securities Exchange Act of 1934 (the Exchange Act) in accord with Section 302 of the Sarbanes-Oxley Act of 2002 (the Section 302 Certification). The Section 302 Certification includes references to an evaluation of the effectiveness of the design and operation of the company's "disclosure controls and procedures" and its "internal controls and procedures for financial reporting". Item 4 of Part I of this Quarterly Report presents the conclusions of the CEO and the CFO about the effectiveness of such controls based on and as of the date of such evaluation (relating to Item 4 of the Section 302 Certification), and contains additional information concerning disclosures to the Company's Audit Committee

and independent auditors with regard to deficiencies in internal controls and fraud (Item 5 of the Section 302 Certification) and related matters (Item 6 of the Section 302 Certification).

The second form of Certification is required by section 1350 of chapter 63 of title 18 of the United States Code.

SIGNATURES

In accordance with the requirements of the Exchange Act, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Discovery Laboratories, Inc.
(Registrant)

Date: November 14, 2002

/s/ Robert J. Capetola

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

Date: November 14, 2002

/s/ John G. Cooper

John G. Cooper
Sr. Vice President, Chief
Financial Officer (Principal
Financial Officer)

Exhibit 99.1

CERTIFICATION

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-14 and 15d-14) for the registrant and we 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 as of a date within 90 days prior to the filing date of this Quarterly Report (the Evaluation Date); and

c) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

By: /s/ Robert J. Capetola

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

Exhibit 99.2

CERTIFICATION

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-14 and 15d-14) for the registrant and we 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 as of a date within 90 days prior to the filing date of this Quarterly Report (the Evaluation Date); and

c) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

By: /s/ John G. Cooper

John G. Cooper
Senior Vice President and
Chief Financial Officer

Exhibit 99.3

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, 2002, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert J. Capetola, President and Chief Executive Officer of the Company, certify, 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.

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and CEO
Date: November 14, 2002

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, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John G. Cooper, Senior Vice President and Chief Financial Officer of the Company, certify, 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.

/s/ John G. Cooper

John G. Cooper
Senior Vice President, CFO
Date: November 14, 2002