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

FORM 10-Q

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

For the quarterly period ended June 30, 2003

OR

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

For the transition period from _____________ to ___________

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	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 |_|

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

As of August 11, 2003, 41,270,576 shares of common stock, par value $.001 per share, were outstanding.

Table of Contents

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

Safe Harbor Statement Under the Private Securities Litigation Act of 1995

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

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin(R), will not prove to be safe or useful for the treatment of certain indications); clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the other risks and uncertainties 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, whether as a result of new information, future events or otherwise.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

Condensed Consolidated Balance Sheets

	June 30, 2003 (Unaudited)	December 31, 2002
Current assets:		
Cash and cash equivalents	$ 31,213,000	$ 8,538,000
Available -for-sale marketable securities	4,300,000	10,652,000
Note receivable - current	2,000	2,000
Prepaid expenses and other current assets	471,000	325,000
Total current assets	35,986,000	19,517,000
Property and equipment, net of accumulated depreciation	1,433,000	1,231,000
Note receivable	194,000	195,000
Other assets	95,000	119,000
Total Assets	$ 37,708,000	$ 21,062,000
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accured expenses	$ 2,693,000	3,013,000
Capitalized lease - current	232,000	189,000
Total current liabilities	2,925,000	3,202,000
Deferred revenue	1,032,000	1,393,000
Credit facility with corporate partner	1,758,000	1,450,000
Capitalized lease, net of current portion	290,000	256,000
Total Liabilities	6,005,000	6,301,000
Shareholders' equity:		
Common stock, $.001 par value; 60,000,000 authorized; 38,492,051 and 32,818,283 issued and outstanding at June 30, 2003 and December 31, 2002, respectively	39,000	33,000
Additional paid-in capital	113,718,000	87,463,000
Unearned portion of compensatory stock options	(12,000)	(95,000)
Deficit accumulated during development stage	(81,932,000)	(72,578,000)
Treasury stock (at cost; 38,243 shares common)	(239,000)	(239,000)
Accumulated other comprehensive income	129,000	177,000
Total shareholders' equity	31,703,000	14,761,000
Total Liabilities & Equity	$ 37,708,000	$ 21,062,000

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 June 30,		Six Months Ended June 30,		May 18, 1993 (Inception) through
	2003	2002	2003	2002	June 30, 2003
Revenues:					
Contracts, Licensing & Milestones	$ 263,000	$ 783,000	$ 657,000	$ 1,020,000	$ 4,497,000
Expenses:					
Research & Development	4,011,000	3,721,000	7,855,000	6,326,000	50,571,000
General & Administrative	1,137,000	1,538,000	2,304,000	2,670,000	25,729,000
Write-off of acquired in-process research and development and supplies	--	--	--	--	13,508,000
Total Expenses	5,148,000	5,259,000	10,159,000	8,996,000	89,808,000
Operating Loss	(4,885,000)	(4,476,000)	(9,502,000)	(7,976,000)	(85,311,000)
Other income and expenses:					
Interest Income, dividends, realized gains, and other income	98,000	191,000	266,000	351,000	4,342,000
Minority interest in net loss of subsidiary	--	--	--	--	26,000
Interest expense	(62,000)	(2,000)	(118,000)	(32,000)	(306,000)
Net Loss	$(4,849,000)	$(4,287,000)	$(9,354,000)	$ (7,657,000)	$(81,249,000)
Net loss per common share - basic and diluted	$ (0.14)	$ (0.16)	$ (0.28)	$ (0.29)	
Weighted average number of common shares outstanding - basic and diluted	33,487,135	26,394,013	33,171,701	26,113,947	

See notes to condensed consolidated financial statements

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

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002	May 18, 1993 (Inception) through June 30, 2003
Cash flows from operating activities:			
Net loss	$ (9,354,000)	$ (7,657,000)	$(81,249,000)
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	178,000	145,000	1,007,000
Compensatory stock options	99,000	169,000	3,676,000
Expenses paid using treasury stock and common stock	--	26,000	230,000
Loss on sale of property	--	--	4,000
Changes in:			
Prepaid expenses and other current assets	(146,000)	(21,000)	690,000
Accounts payable and accrued expenses	(320,000)	(80,000)	2,559,000
Other liabilities	--	400,000	--
Other assets	(1,000)	(2,000)	(24,000)
Proceeds from research and development collaborative agreements	--	1,833,000	3,474,000
Amortization of deferred revenue	(361,000)	(547,000)	(2,997,000)
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	(9,905,000)	(5,734,000)	(58,540,000)
Cash Flows from Investing Activities:			
Purchase of property and equipment	(165,000)	(282,000)	(2,143,000)
Proceeds from sale of property and equipment	--	--	575,000
Loan to related party	--	--	(200,000)
Related party loan payments received	1,000	1,000	4,000
Acquisition of licenses	--	--	(711,000)
Purchase of marketable securities	(209,000)	(5,243,000)	(52,713,000)
Proceeds from sale or maturity of marketable securities	6,513,000	7,500,000	48,947,000
Net cash payments on merger	--	--	(1,670,000)
Net cash provided by (used in) investing activities	6,140,000	1,976,000	(7,911,000)
Cash Flows from Financing Activities:			
Proceeds from issuance of securities, net of expenses	26,245,000	2,923,000	96,254,000
Proceeds from credit facility	308,000	--	1,758,000
Purchase of treasury stock	--	--	(121,000)
Principal payments under capital lease obligation	(113,000)	(22,000)	(227,000)
Net cash provided by financing activities	26,440,000	2,901,000	97,664,000
Net increase (decrease) in cash and cash equivalents	22,675,000	(857,000)	31,213,000
Cash and cash equivalents - beginning of period	8,538,000	3,758,000	--
Cash and cash equivalents - end of period	$ 31,213,000	$ 2,901,000	$ 31,213,000
Supplementary disclosure of cash flows information:			
Interest paid	$ 84,000	$ (32,000)	$ 216,000
Noncash transactions:			
Class H warrants issued/revalued	--	(643,000)	150,000
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	190,000	--	749,000
Unrealized (loss) gain on marketable securities	(48,000)	11,000	129,000
Common and treasury stock issued as payment for services	--	26,000	99,000

See notes to condensed consolidated financial statements

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

The Company

Discovery Laboratories, Inc. (the "Company"), is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders. We believe that our proprietary surfactant technology is the only surfactant technology presently available to potentially treat a broad range of respiratory diseases.

Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactant is involved in a number of respiratory diseases. Our surfactant technology produces an engineered version of natural human lung surfactant that is designed to precisely mimic the essential properties of human lung surfactant.

Our lead product, Surfaxin(R), is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. Surfaxin is currently in a pivotal Phase 3 clinical trial for Respiratory Distress Syndrome in premature infants, a Phase 3 and a Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults. Inhalable aerosolized formulations of our humanized surfactant are presently being developed to potentially treat patients suffering from severe acute asthma and Acute Lung Injury, our lead preclinical programs, as well as COPD, sinusitis, and upper airway disorders such as sleep apnea and otitis media (inner ear infection).

We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp., to commercialize Surfaxin in neonatal indications in the United States. We have also entered into a strategic alliance with Laboratorios del Dr. Esteve to commercialize Surfaxin in Europe and Latin America. We intend to establish strategic alliances, where appropriate, for the development and commercialization of our products in other indications and markets.

Stock Based Employee Compensation

The Financial Accounting Standards Board has issued Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition to a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on the reported results. We continue to account for our stock option plans in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Had we accounted for our stock option plans in accordance with SFAS 123, the pro forma net loss for the six months ended June 30, 2003 and 2002 would have been as follows:

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Net loss as reported	$(9,354,000)	$(7,657,000)
Additional stock-based employee compensation	$ (357,000)	$ (508,000)
Pro forma net loss	$(9,711,000)	$(8,165,000)
Pro forma net loss per share	$ (0.29)	$ (0.31)

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 six-month period ended June 30, 2003, are not necessarily indicative of the results that may be expected for the year ended December 31, 2003. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2002.

We are a development stage company and have incurred substantial losses since inception. To date, we have funded our operations primarily through the issuance of equity. We expect 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 our existing capital, our secured credit facilities with PharmaBio Development Inc., a subsidiary of Quintiles, and General Electric Capital Corporation, and, if possible, to secure additional capital through the issuance of equity and/or collaborative arrangements. Our continuation is dependent on our ability to obtain additional financing and, ultimately, on our ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that our efforts ultimately will be successful.

All of our 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 $4,834,000 and $9,402,000 for the three and six months ended June 30, 2003, respectively, and approximately $4,155,000 and $7,646,000 for the three and six months ended June 30, 2002, respectively.

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

Overview

Since our inception, we have incurred significant losses and, as of June 30, 2003, had a deficit accumulated during the development stage of approximately $81.9 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, financial, business development, legal and general corporate activities and related expenses.

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 our research and development activities will be the clinical trials for Surfaxin indications and related regulatory filings. We are presently conducting a pivotal, multinational landmark Phase 3 trial treating up to 1,500 patients for the treatment of Respiratory Distress Syndrome in premature infants. This pivotal trial is intended, if successful, to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities. This pivotal trial is expected to be completed and data announced early in the fourth quarter of 2003. We have concluded enrollment and reported results of key endpoints of a supportive Phase 3 multinational clinical trial of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants. Further evaluation of secondary endpoints and safety parameters of this supportive clinical trial are currently being conducted. For Acute Respiratory Distress Syndrome in adults, we currently are conducting a Phase 2 dose-ranging safety and efficacy study of up to 110 patients in the United States. We expect to complete this trial in the second quarter of 2004. 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 now anticipated in 2004. 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 the Meconium Aspiration Syndrome program to the Respiratory Distress Syndrome program, as needed. We are conducting a Phase 2 clinical trial of Surfaxin lavage in up to 60 infant patients for use as a prophylactic for infants who are at risk for Meconium Aspiration Syndrome. The clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in the "Risks Related to Our Business" section: "The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain"; and "Our technology platform is based solely on our proprietary humanized, engineered surfactant technology and only our lead product candidate, Surfaxin, has been subject to clinical studies. Our ongoing late-stage clinical trials for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants may be delayed, or fail, which will harm our business."

Aerosolized formulations of our humanized surfactant are presently being developed to potentially treat hospitalized patients suffering from severe acute asthma and Acute Lung Injury. In addition, we are evaluating the development of aerosolized formulations of our humanized surfactant to potentially treat COPD, sinusitis, sleep apnea and otitis media (inner ear infection).

(ii) invest in and support a long-term manufacturing strategy that includes utilizing the clinical and commercial supply capabilities of our current contract manufacturer and securing additional manufacturing capability in order to provide backup for the production of our humanized surfactant drug product and to scale up to meet clinical and commercial needs as they expand.

(iii) invest in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

(iv) 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.

We are currently implementing the initial phase of our long-term manufacturing strategy through the recent selection of Laureate Pharma, L.P., to become our current contract manufacturer. Laureate Pharma will replace our previous contract manufacturer, Akorn, Inc., who has been experiencing operational and financial difficulties. Laureate Pharma has current Good Manufacturing Practices (cGMP)-compliant manufacturing facilities in Princeton and Totowa, New Jersey, and experience in producing sterile pharmaceutical and biopharmaceutical products. In connection with the first phase of the implementation plan with Laureate Pharma, we have transferred our existing manufacturing equipment from Akorn. Plans include having Laureate Pharma produce clinical material by the fourth quarter of 2003. This arrangement also encompasses plans for manufacturing scale-up and enhancements, including additional equipment to support commercial-scale Respiratory Distress Syndrome requirements and Acute Respiratory Distress late-stage, clinical-scale production of Surfaxin. We are currently negotiating the final terms and conditions of a definitive manufacturing agreement with Laureate

Pharma. Until the execution of said agreement, Laureate Pharma is not obligated to manufacture any of our drug products. There can be no assurance that we and Laureate Pharma will ultimately execute such agreement nor that such agreement ultimately will be on terms favorable to us. If the agreement is not executed, we may pursue alternative manufacturing arrangements, which may delay or impair our ability to obtain regulatory approval for our products or be available only on terms that are not favorable to us. See "Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitors drug product, which may not be readily available"; and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

We have entered into a collaboration arrangement with Quintiles, and its affiliate, PharmaBio, 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 will make available up to $70 million in post-launch funding to cover the first seven years of United States sales and marketing costs. In return, Quintiles will receive a commission on net sales of Surfaxin over a 10-year period. The Quintiles arrangement allows us to retain product ownership and have sales and marketing expertise in place for the commercialization of Surfaxin in the United States, if approved.

We have an alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America. Esteve will 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. Our exclusive supply agreement with Esteve provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for the 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 for Surfaxin.

We will need to generate significant revenues from product sales and/or related royalties and transfer prices to achieve and maintain profitability. Through June 30, 2003, we have had no revenues from any 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 contract manufacturers and suppliers, including, without limitation, our contract manufacturing facility. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through June 30, 2003, we had not generated taxable income. At December 31, 2002, net operating losses available to offset future taxable income for federal tax purposes were approximately $65.1 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, 2002, we had a research and development tax credit carryforward of $1,225,000. 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 six months ended June 30, 2003 were $4,849,000 ($0.14 per common share) and $9,354,000 ($0.28 per common share), respectively. Net loss for the three and six months ended June 30, 2002 were $4,287,000 ($0.16 per common share) and $7,657,000 ($0.29 per common share), respectively.

Revenues

Revenues from research and development collaborative contracts for the three and six months ended June 30, 2003 were $263,000 and $657,000, respectively. Revenues from research and development collaborative contracts for the three and six months ended June 30, 2002 were $783,000 and $1,020,000, respectively. The decreased revenues are related to (i) the conclusion of work associated with our Small Business Innovative Research (SBIR) grant for research in 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;

and (ii) the extension of the amortization period and related revenue recognition of the funding previously provided to us in connection with our strategic alliance with Esteve which now reflects the planned fourth quarter 2003 completion of our Phase 3 pivotal clinical trial for Surfaxin for Respiratory Distress Syndrome in premature infants.

Expenses

Research and development expenses for the three and six months ended June 30, 2003 were $4,011,000 and $7,855,000, respectively. Research and development expenses for the three and six months ended June 30, 2002 were $3,721,000 and $6,326,000, respectively. This increase primarily reflects clinical trial costs incurred for our lead product, Surfaxin, currently in various Phase 3 and Phase 2 clinical trials for critical care patients with life threatening respiratory disorders, and research and development activities related to the development of aerosolized formulations of our humanized lung surfactant to potentially treat a variety of respiratory and upper airway conditions.

General and administrative expenses for the three and six months ended June 30, 2003 were $1,137,000 and $2,304,000, respectively. General and administrative expenses for the three and six months ended June 30, 2002 were $1,538,000 and $2,670,000, 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 are approximately $310,000 and $400,000 for the six months ended June 30, 2003 and 2002, respectively, related to 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"). Additionally, included general and administrative costs are non-cash compensation charges of approximately $99,000 and $346,000 for the six months ended June 30, 2003 and 2002, respectively, related to options granted to non-employee directors under the Automatic Option Grant Program of our Amended and Restated 1998 Stock Option Plan.

Other Income and Expense

Other income and expense (net) for the three and six months ended June 30, 2003 were $36,000 and $148,000, respectively. Other income and expense (net) for the three and six months ended June 30, 2002 were $189,000 and $319,000. The decrease in other income and expense (net) is due primarily to interest expense associated with our secured, revolving credit facility and capital lease financing arrangements and a decrease in interest earned on our cash, cash equivalents and marketable securities primarily due to a general reduction in earned market interest rates. See "Liquidity and Capital Resources."

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

As of June 30, 2003, we had cash, cash equivalents and marketable securities of approximately $35.5 million as compared to approximately $19.2 million we had as of December 31, 2002. As of June 30, 2003, we had working capital of approximately $33.0 million as compared to the working capital of approximately $16.3 million we had as of December 31, 2002. The increase in working capital is due to the net proceeds of $26.1 million received from the sale of securities offset by funds used in our clinical trial and research and development activities.

In June and July of 2003, our common stock attained certain price performance thresholds on the Nasdaq SmallCap Market that permitted us to provide notice for redemption (and thereby effectively compel the exercise thereof) to the holders of three of our outstanding classes of warrants which represented, in aggregate, the right to purchase approximately 3.6 million shares of common stock. Such warrants (i.e., the Class I, Class F and Class C warrants) were previously issued by us in connection with certain private placement financings that occurred in November 2002, October 2001 and April 1999, respectively. As of August 12, 2003, warrants representing 2.8 million shares of common stock out of the total of approximately 3.6 million shares of common stock issuable upon exercise of such warrants have been exercised, in accordance with their terms, either cashlessly or for cash resulting in approximately 2.6 million shares of common stock issued to such warrantholders and aggregate cash proceeds of approximately $5.7 million received by us.

Secured, Revolving Credit Facility and Capital Lease Financing Arrangements

We have 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 our satisfaction of certain conditions. We have satisfied the conditions for availability of the first two tranches and at June 30, 2003, the amount available under the credit facility was approximately $5.7 million, of which $1.8 million was outstanding. 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. 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.

We have a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation that provides, subject to certain conditions, for up to $1 million in financing for capital purchases. As of June 30, 2003, we had used approximately $475,000 of this financing arrangement.

Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, levels of resources that our collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors, our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Historically, our working capital has been provided from the proceeds of private financings:

In June 2003, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately $26.1 million. We issued 4,997,882 shares of common stock and 999,577 Class A Investor warrants to purchase shares of common stock at an exercise price of $6.875 per share. The Class A Investor warrants have a seven-year term. See Part II Item 2: "Change in Securities and use of Proceeds."

In November 2002, we completed the sale of securities in a private placement to selected institutional and accredited investors for net proceeds of approximately $11.9 million. We issued 6,397,517 shares of common stock and 2,878,883 Class I warrants to purchase shares of common stock at an exercise price of $2.425 per share. The Class I warrants have a five-year term and we are entitled to redeem the Class I warrants, with 60 days' prior written notice, for $.001, upon the attainment of certain exchange-related price performance thresholds of the common stock. In June 2003, the price performance criteria was met and we provided notice to the Class I warrantholders of our intention to redeem the Class I warrants. As of August 11, 2003, 726,726 Class I warrants remain unexercised.

Pursuant to our collaboration arrangement with Esteve on March 6, 2002, we issued 821,862 shares of common stock to Esteve at a purchase price equal to $4.867 per share and received a licensing fee of $500,000, for approximate net aggregate proceeds of $4.45 million.

Pursuant to the collaboration arrangement we entered into with Quintiles and PharmaBio in December 2001, we issued to PharmaBio, for approximate net aggregate proceeds of $2.7 million: (i) 791,905 shares of common stock at a price equal to $3.79 per share; and (ii) Class G warrants to purchase 357,143 shares of common stock at an exercise price equal to $3.485 per share (subject to adjustment). 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.

In October 2001, we received approximately $7.3 million in net proceeds from a private financing. In the financing, we issued 3,562,759 shares of common stock and 712,553 Class F warrants to purchase shares of common stock at an exercise price equal to $2.365 per share. The Class F warrants have a five-year term and we are entitled to redeem the Class F warrants, with 20 days' prior written notice, for $.001, upon the attainment of certain exchange-related price performance thresholds of the common stock. In July 2003, the price performance criteria was met and we provided notice to the Class F warrantholders of our intention to redeem the Class F warrants. As of August 11, 2003, 104,552 Class F warrants remain unexercised.

In April 2001, we received approximately $1 million in 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 in a private placement offering from the sale of 2,902,846 shares of common stock and 580,567 Class E warrants to purchase common stock at $7.38 per share. The Class E warrants issued in the offering 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 $2,233,000 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. In August 2003, pursuant to the terms of the Class C warrants, we provided notice to the Class C warrantholders of our intention to redeem the Class C warrants. As of August 11, 2003, 56,907 Class C warrants remain unexercised.

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, including amounts currently available under our credit facility with PharmaBio, and our capital lease financing arrangement with General Electric Capital Corporation, will be adequate to satisfy our capital needs into 2005. 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. Other than our credit facility with PharmaBio and our capital lease financing arrangement with General Electric Capital Corporation, 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 - We will need additional capital, and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution"; "The market price of our stock may be adversely affected by market volatility"; and "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."

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

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of June 30, 2003, we have incurred a deficit accumulated during the development stage of approximately $81.9 million, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary humanized, engineered surfactant technology and only our lead product candidate, Surfaxin, has been subject to clinical studies. Our ongoing late-stage clinical trials for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants may be delayed, or fail, which will harm our business.

Our humanized, engineered surfactant platform technology is based on the scientific rationale for surfactant replacement therapy to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Our lead product, Surfaxin, is currently in a Phase 3 clinical trial 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.

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

- -- the number of clinical sites;

- -- the size of the patient population;

- -- the proximity of patients to the clinical sites;

- -- the eligibility criteria for the study;

- -- the existence of competing clinical trials; and

- -- the existence of alternative available products.

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

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

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

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

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 is expensive and time consuming, and the outcome is uncertain.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials.

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

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

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 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. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin, Meconium Aspiration Syndrome in full-term infants, Acute Respiratory Distress Syndrome in adults and Respiratory Distress Syndrome in infants. To support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years. 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.

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

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. We recently transferred our manufacturing capabilities from our single validated clinical manufacturing facility, owned and operated by Akorn to a new contract manufacturer, Laureate Pharma, with the objective of producing appropriate clinical grade material of our drug substance that meet the standards for use in our ongoing clinical studies. We are currently negotiating the final terms and conditions of a definitive manufacturing agreement with Laureate Pharma. Until the execution of said agreement, Laureate Pharma is not obligated to manufacture any of our drug products. There can be no assurance that we and Laureate Pharma will ultimately execute such agreement nor that such agreement ultimately will be on terms favorable to us. If the agreement is not executed, we may pursue alternative manufacturing arrangements, which may delay or impair our ability to obtain regulatory approval for our products or be available only on terms that are not favorable to us.

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

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, we have no validated clinical manufacturing facility to produce appropriate clinical grade material of our drug substance for use in our ongoing clinical studies.

Laureate Pharma or other outside manufacturers may not be able to (i) produce our drug substance to appropriate standards for use in clinical studies, (ii) perform under the definitive manufacturing agreement once such agreements are executed, if at all, or (iii) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or 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 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. In March 2002, we expanded our relationship with Esteve by entering into a collaboration arrangement with Esteve for Surfaxin covering all of Europe and Latin America. Esteve will be responsible for the marketing of Surfaxin for the 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 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.

In December 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 and Meconium Aspiration Syndrome. 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 or other terms and conditions of the financing leading to PharmaBio's termination thereof or the failure by PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

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

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson, 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 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to Our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

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

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

We depend on licensing 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. 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.

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, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe and Latin America. 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, either 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 from 2003 through 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

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

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

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

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

- -- developing products;

- -- undertaking preclinical testing and human clinical trials;

- -- obtaining FDA and other regulatory approvals or products; and

- -- manufacturing and marketing products.

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

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

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Exosurf(R) is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. Curosurf(R) is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta(R), marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf(R) 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.

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 June 30, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 9% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of

Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- -- announcements of the results of clinical trials by us or our competitors;

- -- adverse reactions to products;

- -- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;

- -- changes in the United States or foreign regulatory policy during the period of product development;

- -- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;

- -- announcements of technological innovations by us or our competitors;

- -- announcements of new products or new contracts by us or our competitors;

- -- actual or anticipated variations in our operating results due to the level of development expenses and other factors;

- -- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

- -- conditions and trends in the pharmaceutical and other industries;

- -- new accounting standards; and

- -- the occurrence of any of the risks described in this "Management's Discussion and Analysis - Risks Related to Our Business."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the six-month period ended June 30, 2003, the price of our common stock has ranged from $1.32 to $7.40. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the six-month period ending June 30, 2003, the average daily trading volume in our common stock was approximately 245,188 shares and the average number of transactions per day was approximately 329. 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 the 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 June 30, 2003, we had 38,492,051 shares of common stock issued and outstanding. In addition, as of June 30, 2003, up to approximately 11,465,000 shares of our common stock were issuable upon 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, including large blocks of preferred stock. 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.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer. We currently do not hedge interest rate or currency exchange exposure. We classify highly liquid investments purchased with a maturity of three months or less as "cash equivalents" and commercial paper and fixed income mutual funds as "available for sale securities." Fixed income securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive and financial officers reviewed and evaluated our disclosure controls and procedures (as defined in Rule 13a-14 promulgated under the Securities Exchange Act of 1934) prior to the filing of this Quarterly Report. Based on that evaluation, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in timely providing them with material information, as required to be disclosed in the reports we file pursuant to the Exchange Act.

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

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 2. CHANGE IN SECURITIES AND USE OF PROCEEDS.

In the quarter ended June 30, 2003, we granted an aggregate of 61,250 options to our employees and consultants at various exercise prices ranging from $1.710 per share to $4.989 per share. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker/dealers were involved in the sale and no commissions were paid.

In the quarter ended June 30, 2003, pursuant to a financing, we issued units consisting of an aggregate of approximately 5.0 million shares of common stock, par value $.001 per share, and Class A Investor warrants to purchase an aggregate of approximately 1.0 million shares of common stock with an initial exercise price of $6.875 per share of common stock. We anticipate using the net proceeds of approximately $26.5 million generated from the financing for working capital and for other general corporate purposes, primarily the continuing research and development of our products.

The Offering was not registered under the Securities Act in reliance on the exceptions set forth in Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. Each of the purchasers in the financing represented that it is an accredited investor, as defined by Rule 501 promulgated under the Securities Act, and certificates representing the shares of common stock and the Class A Investor warrants issued in connection with the financing will contain appropriate legends to reflect the restrictions on transfer imposed by the Securities Act.

In the quarter ended June 30, 2003, pursuant to the exercise of outstanding warrants described in this Quarterly Report, we issued an aggregate of 675,886 shares of our common stock at various exercise prices ranging from $0.0821 per share to $3.53 per share. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker/dealers were involved in the sale and no commissions were paid.

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:

- 31.1 Section 302 Certification of Chief Executive Officer
- 31.2 Section 302 Certification of Chief Financial Officer
- 32 Section 906 Certification of Chief Executive Officer and Chief Financial Officer

(b) Reports on Form 8-K:

Three current reports on Form 8-K were filed in the second quarter of 2003. The first on May 21, 2003, announcing financial results for the first quarter of 2003, the second on June 5, 2003, announcing the conclusion of enrollment and results of key endpoints of our supportive Phase 3 multinational clinical trial of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants and the third on June 19, 2003, announcing the completion of a private placement in which we raised approximately $27.5 million in gross proceeds.

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

Exhibits 31.1, 31.2 and 32 to this Quarterly Report on Form 10-Q include Certifications of our Chief Executive Officer and our Chief Financial Officer.

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

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: August 14, 2003

/s/ Robert J. Capetola

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

Date: August 14, 2003

/s/ John G. Cooper

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

Exhibit 31.1

CERTIFICATIONS

I, Robert J. Capetola, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;

2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

c) disclosed in this Quarterly Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: August 14, 2003

By: /s/ Robert J. Capetola

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

Exhibit 31.2

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;

2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

c) disclosed in this Quarterly Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Date: August 14, 2003

By: /s/ John G. Cooper

John G. Cooper
Senior Vice President and
Chief Financial Officer

Exhibit 32

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 June 30, 2003, as filed with the Securities and Exchange Commission (the "Commission") on the date hereof (the "Report"), each of the undersigned, in his capacity as an officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer
Date: August 14, 2003

/s/ John G. Cooper

John G. Cooper
Senior Vice President and Chief Financial Officer
Date: August 14, 2003