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, 2004

OR

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

For the transition period from _____ to _____
Commission file number 000-26422

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

DELAWARE	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. |X|Yes |_|No

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

As of July 31, 2004, 46,941,379 shares of common stock, par value $.001 per share, were outstanding.

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

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995

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

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; delays in our preparation and filing of applications with the FDA for regulatory approval; delays in the FDA's approval of any applications we file with the FDA, including the NDA we filed in April 2004; potential rejection of any applications we file with the FDA, including the NDA we filed in April 2004; 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), or other drug candidates will not prove to be safe or useful for the treatment of certain indications); clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators 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 of Financial Condition and Results of Operations" and in any documents incorporated by reference in this report.

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	JUNE 30, 2004 (Unaudited)	DECEMBER 31, 2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 23,527,000	$ 29,422,000
Available-for-sale marketable securities	17,782,000	--
Note receivable - current portion	2,000	3,000
Prepaid expenses and other current assets	1,269,000	665,000
Total Current Assets	42,580,000	30,090,000
Property and equipment, net of accumulated depreciation	2,922,000	2,414,000
Note receivable, net of current portion	191,000	192,000
Other assets	19,000	19,000
Total Assets	$ 45,712,000	$ 32,715,000
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,652,000	$ 4,210,000
Credit facility with corporate partner	4,811,000	2,436,000
Capitalized lease - current portion	559,000	383,000
Total current liabilities	10,022,000	7,029,000
Deferred revenue	403,000	672,000
Capitalized lease, net of current portion	1,187,000	711,000
Total Liabilities	11,612,000	8,412,000
Stockholders' Equity:		
Common stock, $.001 par value; 80,000,000 authorized; 46,914,379 and 42,491,438 issued and outstanding at June 30, 2004 and December 31, 2003, respectively	47,000	43,000
Additional paid-in capital	152,275,000	122,409,000
Unearned portion of compensatory stock options	(577,000)	(2,000)
Accumulated deficit	(114,627,000)	(96,858,000)
Treasury stock (at cost; 307,604 and 167,179 shares at June 30, 2004 and December 31, 2003, respectively)	(3,000,000)	(1,289,000)
Accumulated other comprehensive income	(18,000)	--
Total Stockholders' Equity	34,100,000	24,303,000
Total Liabilities & Stockholders' Equity	$ 45,712,000	$ 32,715,000

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2004	2003	2004	2003
Revenues:				
Contracts, Licensing, Grants & Milestones	$ 697,000	$ 263,000	$ 839,000	$ 657,000
Expenses:				
Research & Development	6,123,000	4,011,000	12,833,000	7,855,000
General & Administrative	3,425,000	1,137,000	5,706,000	2,304,000
Total Expenses	9,548,000	5,148,000	18,539,000	10,159,000
Operating Loss	(8,851,000)	(4,885,000)	(17,700,000)	(9,502,000)
Other income and expenses:				
Interest income, dividends, realized gains, and other income	209,000	98,000	272,000	266,000
Interest and amortization expense	(255,000)	(62,000)	(341,000)	(118,000)
Net Loss	$ (8,897,000)	$ (4,849,000)	$(17,769,000)	$ (9,354,000)
Net loss per common share - basic and diluted	$ (0.19)	$ (0.14)	$ (0.39)	$ (0.28)
Weighted average number of common shares outstanding - basic and diluted	46,683,195	33,487,135	45,003,327	33,171,701

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	SIX MONTHS ENDED JUNE 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	$(17,769,000)	$ (9,354,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	252,000	178,000
Compensatory stock options	512,000	99,000
Changes in:		
Prepaid expenses and other current assets	(630,000)	(146,000)
Accounts payable and accrued expenses	442,000	(320,000)
Other assets	--	(1,000)
Amortization of deferred revenue	(269,000)	(361,000)
Net cash used in operating activities	(17,462,000)	(9,905,000)
Cash flows from investing activities:		
Purchase of property and equipment	(760,000)	(355,000)
Related party loan payments received	2,000	1,000
Purchase of marketable securities	(17,800,000)	(209,000)
Proceeds from sale or maturity of marketable securities	--	6,513,000
Net cash (used in) provided by investing activities	(18,558,000)	5,950,000
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	27,098,000	26,245,000
Proceeds from credit facility	2,375,000	308,000
Proceeds from capital lease arrangement	866,000	190,000
Principal payments under capital lease obligation	(214,000)	(113,000)
Net cash provided by financing activities	30,125,000	26,630,000
Net (decrease) increase in cash and cash equivalents	(5,895,000)	22,675,000
Cash and cash equivalents - beginning of period	29,422,000	8,538,000
Cash and cash equivalents - end of period	$ 23,527,000	$ 31,213,000
Supplementary disclosure of cash flows information:		
Interest paid	$ 92,000	$ 84,000
Noncash transactions:		
Class H warrants issued/revalued	(26,000)	--
Unrealized loss on marketable securities	(18,000)	(48,000)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

THE COMPANY

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and are essential for breathing. The absence or depletion of surfactants is involved in a number of respiratory diseases. Our technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. We believe that through this technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

In April 2004, we have filed a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) for clearance to market Surfaxin(R), our lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. On June 15, 2004, we announced that the FDA had accepted the NDA filing for Surfaxin for the prevention of RDS in premature infants and had granted a Standard Review designation establishing a target date of February 13, 2005, for the completion of its review of the NDA.

Our Surfactant Replacement Therapy (SRT) is also in a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults, as well as in a Phase 3 and a Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome (MAS) in full-term infants. With aerosolized surfactant formulations, we are preparing to initiate a Phase 2 trial for asthma (development name DSC-104) and a Phase 2 trial using aerosolized surfactant in combination with Nasal Continuous Positive Airway Pressure (nasal CPAP) for neonatal pulmonary disorders.

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

STOCK BASED EMPLOYEE COMPENSATION

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net Loss as Reported	$ (8,897,000)	$ (4,849,000)	$(17,769,000)	$ (9,354,000)
Additional stock-based employee compensation	$ (2,740,000)	$ (91,000)	$ (2,740,000)	$ (357,000)
Pro forma net loss	$(11,637,000)	$ (4,940,000)	$(20,509,000)	$ (9,711,000)
Pro forma net loss per share	$ (0.25)	$ (0.15)	$ (0.46)	$ (0.29)

BASIS OF PRESENTATION

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

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

Certain prior year balances have been reclassified to conform with the current presentation.

NOTE 2 - NET LOSS PER SHARE

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

NOTE 3 - COMPREHENSIVE LOSS

Total comprehensive loss was approximately $8,915,000 and $17,787,000 for the three and six months ended June 30, 2004, respectively, and approximately $4,834,000 and $9,402,000 for the three and six months ended June 30, 2003, respectively.

NOTE 4 - NOTE RECEIVABLE

Note receivable pertains to a $200,000, 7% per annum mortgagor's note due from one of our executive officers. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly payments of principal and interest over a 360-month period. The principal balance outstanding at June 30, 2004 and December 31, 2003 was approximately $193,000 and $195,000, respectively.

NOTE 5 - TREASURY STOCK

During the six months ended June 30, 2004, certain members of our management and certain consultants, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tendered shares of common stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the six months ended June 30, 2004, 140,425 shares of our common stock were tendered to us by such parties in lieu of cash at a weighted average price of $12.02 per share. These shares are accounted for as treasury stock. See "Liquidity and Capital Resources".

NOTE 6 - SUBSEQUENT EVENTS

In July 2004, we entered into a Committed Equity Financing Facility Arrangement (CEFF) with Kingsbridge Capital Limited pursuant to which Kingsbridge has committed to finance up to $75 million of capital to support our future growth. Subject to certain limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of our common stock. Subject to certain conditions and limitations, the CEFF allows us to raise capital as required, at the time, price and in amounts deemed suitable to us, during the three-year period following the effectiveness of the registration statement to be filed with the Securities and Exchange Commission in connection with the CEFF.

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, 2004, we had an accumulated deficit of approximately $115 million. The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, business and commercial development, financial, legal and general corporate activities. See "Results of Operations."

We have funded our operations with working capital provided principally through public and private equity financings and strategic collaborations. As of June 30, 2004, we had cash and investments of approximately $41.3 million, an $8.5 million secured revolving credit facility with PharmaBio Development, Inc., a subsidiary of Quintiles Transnational Corp., of which $4.8 million was outstanding, and a $4.0 million capital equipment lease financing arrangement, of which approximately $2.0 million was available for borrowing, $2.0 million had been used, and $1.7 million was outstanding.

In April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.8 million, respectively. See "Liquidity and Capital Resources".

PLAN OF OPERATIONS

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

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

(i) increase our research, development and regulatory activities in an effort to further develop our existing pipeline products and broaden our pipeline of potential Surfactant Replacement Therapies for respiratory diseases.

We completed two Phase 3 clinical trials of Surfaxin for the prevention of RDS in premature infants, filed an NDA with the FDA and are preparing to file a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMEA). Also, in accordance with the trial design for both Phase 3 studies, we continue to conduct six and twelve month clinical follow-up on all enrolled patients in such Phase 3 clinical trials. For ARDS, we are currently 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 fourth quarter of 2004. For Meconium Aspiration Syndrome in full-term infants, we are currently conducting a Phase 3 clinical trial in up to 200 patients and a Phase 2 clinical trial in up to 60 patients. We recently completed a successful Phase 1b clinical trial intended to evaluate the safety, tolerability and lung deposition of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma. We intend to initiate a Phase 2 clinical trial late in 2004 for patients with moderate to severe asthma. We are also preparing to initiate a Phase 2 clinical trial in late 2004, using aerosolized formulations of our humanized surfactant in combination with nasal CPAP to treat premature infants in Neonatal Intensive Care Units (NICU) suffering from pulmonary disorders. In addition, we are evaluating the development of aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, COPD, rhinitis, sinusitis, sleep apnea and otitis media (inner ear infection).

The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in the "Risks Related to Our Business"- "Our technology platform is based solely on our proprietary humanized, engineered surfactant technology. Our ongoing clinical trials for our lead surfactant replacement therapies may be delayed, or fail, which will harm our business" and "The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain".

(ii) invest in and support a long-term manufacturing strategy for the production of our humanized surfactant drug product including further development and scale-up at our current contract manufacturer, alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet production needs as they expand.

(iii) invest in marketing and commercialization (including distribution) resources to execute the launch of Surfaxin for the treatment of RDS in premature infants, if approved, and the execution of our "Discovery/Surfaxin" worldwide sales and marketing strategy.

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

Through our contract manufacturer, Laureate Pharma, L.P., we have established a Surfaxin manufacturing line to support the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). This arrangement provides for the commercial-scale requirements of Surfaxin for the prevention of RDS in premature infants and our anticipated clinical-scale production requirements of Surfaxin for the treatment of ARDS in adults. Our manufacturing capability has now provided adequate Surfaxin ARDS product to supply all participating clinical sites in order to complete Part B of the Phase 2 study. In addition to our arrangement with Laureate, we plan to conduct other activities in connection with the implementation of our long term manufacturing strategy including evaluating and establishing additional contract or Discovery-owned manufacturing facilities. See "Risks Related to Our Business" - "In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product which may not be readily available" and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products".

We have a collaboration arrangement with Quintiles and PharmaBio to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. Quintiles is obligated to hire and train a dedicated United States sales force that will be branded in the market as ours. Quintiles has committed to make available up to $70.0 million in post-launch funding to cover the first seven years of United States sales and marketing costs. In return, Quintiles is entitled to 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 capabilities in place for the commercialization of Surfaxin for RDS and MAS in the United States, if approved.

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

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

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

RESULTS OF OPERATIONS

Net loss for the three and six months ended June 30, 2004 were $8,897,000 ($0.19 per common share) and $17,769,000 ($0.39 per common share), respectively. 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.

Revenues

Revenues from research and development collaborative agreements and grants for the three and six months ended June 30, 2004 were $697,000 and $839,000, respectively. Revenues from research and development collaborative agreements and grants for the three and six months ended June 30, 2003 were $263,000 and $657,000, respectively. These revenues are associated with our alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America (whereby Esteve funded a portion of the RDS clinical trial costs and has committed to fund up to $6 million of ARDS development costs) as well as a Small Business Innovative Research (SBIR) grant, which was concluded in 2003, to develop Surfaxin for ALI/ARDS in adults. The amounts recognized for the three and six months ending June 30, 2004, primarily reflects revenue recognized pursuant to the Esteve alliance including $550,000 recognized in the quarter ending June 30, 2004 associated with Esteve's ARDS development commitment. Revenues recognized for the three and six months ending June 30, 2003, primarily reflect work activities pursuant to the SBIR grant for research of ALI/ARDS treatments and revenue recognized in connection with Esteve's funding of the RDS clinical trial costs.

Expenses

Research and development expenses for the three and six months ended June 30, 2004 were $6,123,000 and $12,833,000, respectively. Research and development expenses for the three and six months ended June 30, 2003 were $4,011,000 and $7,855,000, respectively.

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

(i) $1,900,000 and $3,700,000, for the three and six months ended June 30, 2004, respectively, for manufacturing activities to support the production of clinical and commercial drug supply of Surfaxin at Laureate's facility in conformance with cGMPs. There were no comparable costs related to manufacturing activities for the three and six months ended June 30, 2003;

(ii) development activities, including drug supply, for the Phase 2 clinical trial of Surfaxin for the treatment of ARDS in adults;

(iii) development and regulatory efforts for Surfaxin - primarily the Phase 3 clinical trials for Surfaxin for the prevention of RDS in premature infants for which an NDA was filed with the FDA in April 2004; and

(iv) research and development activities of aerosolized formulations of the Company's SRT technology in preparation for the initiation of a Phase 2 clinical trial (anticipated in late 2004) using aerosolized surfactant in combination with nasal CPAP to potentially treat premature infants in the NICU suffering from pulmonary disorders and the initiation of a Phase 2 clinical trial (anticipated in fourth quarter 2004) using DSC-104 to treat patients with moderate to severe asthma.

General and administrative expenses for the three and six months ended June 30, 2004 were $3,425,000 and $5,706,000, respectively. 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 consist primarily of the costs of executive management, business and commercial development, financial and accounting, legal, facility and other administrative costs.

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

(i) Pre-launch commercialization services for RDS of approximately $1,074,000 and $2,010,000, respectively for the three and six months ended June 30, 2004 compared to $110,000 and $310,000, respectively, for the same periods last year. For the three and six months ended June 30, 2004, $846,000 and $1,675,000, respectively, of the pre-launch commercialization costs were incurred pursuant to the collaboration agreement with Quintiles (for which funding is provided by the secured, revolving credit facility with PharmaBio, discussed below in "Liquidity and Capital Resources");

(ii) one time charges during the three months ended June 30, 2004, which include a $250,000 milestone payment to Johnson & Johnson, Inc., payable in accordance with the terms of our sublicense of Surfaxin upon submission of the NDA and a $125,000 fee to have our common stock listed on the NASDAQ National Market (our common stock was previously listed on the NASDAQ SmallCap Market);

(iii) corporate governance initiatives in compliance with the Sarbanes-Oxley Act;

(iv) legal activities related to the preparation and filing of patents and other activities associated with our intellectual property in connection with the expansion of our SRT pipeline; and

(v) non-cash compensation charges of $281,000 and $282,000, respectively, for the three and six months ended June 30, 2004, compared to $87,000 and $99,000, respectively, for the same periods last year, related to stock options granted to employees and consultants under our Amended and Restated 1998 Stock Option Plan.

Other Income and Expense

Interest income for the three and six months ended June 30, 2004 was $209,000 and $272,000 respectively as compared to $98,000 and $266,000 respectively for the three and six months ended June 30, 2003. The increase in interest income is due to a higher average cash, cash equivalent and marketable securities balance.

Interest expense and amortization expense for the three and six months ended June 30, 2004 was $255,000 and $341,000 respectively as compared to $62,000 and $118,000 respectively for the three and six months ended June 30, 2003. The increase is due to interest expense associated with our secured, revolving credit facility and capital lease financing arrangements and amortization expense associated with premiums on our marketable securities. See "Liquidity and Capital Resources".

LIQUIDITY AND CAPITAL RESOURCES

Cash, Cash Equivalents, and Marketable Securities

As of June 30, 2004, we had cash, cash equivalents and marketable securities of approximately $41.3 million as compared to approximately $29.4 million as of December 31, 2003. The increase in cash, cash equivalents and marketable securities from December 31, 2003, is primarily due to: (i) an underwritten public offering of 2,200,000 shares of common stock with gross and net proceeds equal to $24.2 million and approximately $22.8 million, respectively; (ii) $4.3 million received from the exercise of outstanding options and warrants; and (iii) $3.2 million from our secured, revolving credit facility and capital lease financing arrangements. These increases were offset by $17.5 million used in operating activities during the period.

For the quarter ended June 30, 2004, cash and marketable securities increased $17.7 million due to net proceeds of $22.8 million from an underwritten public offering of 2,200,000 shares of common stock in April 2004. Excluding this financing, cash decreased from the previous quarter by $5.1 million due to the use of approximately $8.9 million for operating activities offset by $2.1 million of net proceeds from the use of existing credit and capital lease facilities and $2.0 million received from the exercise of certain options and warrants.

Committed Equity Financing Facility (CEFF)

In July 2004, we entered into a CEFF with Kingsbridge pursuant to which Kingsbridge has committed to finance up to $75 million of capital to support our future growth. Subject to certain limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of our common stock. Subject to certain conditions and limitations, the CEFF allows us to raise capital as required, at the time, price and in amounts deemed suitable to us, during the three-year period following the effectiveness of the registration statement to be filed with the Commission in connection with the CEFF.

Secured, Revolving Credit Facility; and Capital Lease Financing Arrangements

We have a secured revolving credit facility of up to $8.5 to $10 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. At June 30, 2004, we had satisfied the conditions for availability of all tranches, allowing us to access the remaining amounts available under the secured revolving credit facility. As of June 30, 2004, $4.8 million was outstanding under the credit facility. Our use of this credit facility was $1.5 million and $2.4 million for the three and six months ended June 30, 2004, respectively.

Interest on amounts advanced under the PharmaBio credit facility are payable quarterly in arrears. Outstanding principal and interest due under the credit facility are due and payable on December 10, 2004. 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. There can be no assurance that we will achieve any of these milestones prior to the repayment date, and doing so is highly unlikely unless the FDA expedites the review of the NDA for Surfaxin for the treatment of RDS in premature infants that we filed with the FDA in April 2004, and approves such NDA prior to December 10, 2004. See "Risks Related to our Business -The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain". 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 for up to $4.0 million. As of June 30, 2004, approximately $2.0 million remained available for use and approximately $1.7 million was outstanding under this financing arrangement. Use of this financing arrangement was $587,000 and $866,000 for the three and six months ended June 30, 2004, respectively.

Working Capital

With our capital resources as of June 30, 2004, we believe our current working capital is sufficient to meet our planned research and development and operational activities into the second half of 2005, before taking into account any amounts that may be available through use of the CEFF. We will need additional financing from investors or collaborators to complete research and development and commercialization of our current product candidates under development. Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, levels of resources that our collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors, our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

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

In July 2004, we entered into a CEFF with Kingsbridge pursuant to which Kingsbridge has committed to finance up to $75.0 million of capital for newly-issued shares of our common stock. The exact timing, amount and price of any CEFF financings is subject to our ultimate determination, subject to certain conditions. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 375,000 shares of common stock at an exercise price equal to $12.0744 per share. The exercise term of the warrant is five years beginning with the six-month anniversary of the closing date of the agreement. The warrant must be exercised for cash, except in limited circumstances.

In April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.8 million, respectively.

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

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

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

Pursuant to the 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). The Class G warrants had a ten-year term and we were entitled to redeem the Class G warrants upon the attainment of certain exchange-related price performance thresholds of the common stock. In February 2004, the price performance criteria was met and we provided notice to PharmaBio of our intention to redeem the Class G warrants. The Class G warrants were cashlessly exercised resulting in the issuance of 249,726 shares. In connection with the credit facility, we issued to PharmaBio Class H warrants to purchase 320,000 shares of common stock. The Class H warrants are exercisable at $3.03 per share (subject to adjustment) and are exercisable proportionately only upon availability of the credit facility. To the extent the credit facility availability is increased to greater than $8.5 million, for each $1.0 million increase, the amount of shares of common stock issuable pursuant to the Class H warrants shall be increased by approximately 38,000 shares. The Class H warrants had a ten-year term and we were entitled to redeem the Class H warrants upon the attainment of certain exchange-related price performance thresholds of the common stock. In April 2004, the price performance criteria was met and we provided notice to PharmaBio of our intention to redeem the vested portion of the Class H warrants. As of June 30, 2004, the vested portion of the Class H warrants were cashlessly exercised resulting in the issuance of 160,318 shares. Subsequently, on August 4, 2004, the remaining Class H warrants vested, were redeemed and cashlessly exercised resulting in the issuance of 68,084 shares.

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

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

Treasury Stock

During the six months ended June 30, 2004, certain members of our management and certain consultants, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tendered shares of common stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the six months ended June 30, 2004, 140,425 shares of our common stock were tendered to us by such parties in lieu of cash at a weighted average price of $12.02 per share. These shares are accounted for as treasury stock as follows:

	Number of shares received in lieu of cash for the exercise of stock options	Average price per share
January 2004	97,226	$ 12.44
March 2004	18,497	12.08
May 2004	24,702	11.27
Total	140,425	$ 12.02

RISKS RELATED TO OUR BUSINESS

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

BECAUSE WE ARE A BIOPHARMACEUTICAL COMPANY, WE MAY NOT SUCCESSFULLY DEVELOP AND MARKET OUR PRODUCTS, AND EVEN IF WE DO, WE MAY NOT GENERATE ENOUGH REVENUE OR BECOME PROFITABLE.

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

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of June 30, 2004, we have an accumulated deficit of approximately $115.0 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. OUR ONGOING CLINICAL TRIALS FOR OUR LEAD SURFACTANT REPLACEMENT TECHNOLOGIES MAY BE DELAYED, OR FAIL, WHICH WILL HARM OUR BUSINESS.

Our humanized, engineered surfactant platform technology is based on the scientific rationale of SRT to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently we completed and filed an NDA with the FDA from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the prevention of RDS in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and a Phase 3 and a Phase 2 clinical trial for the treatment of MAS in full-term infants. We recently completed a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. We are preparing for the initiation of a Phase 2 clinical trial using aerosolized surfactant in combination with nasal CPAP to potentially treat premature infants in the NICU suffering from pulmonary disorders and a Phase 2 trial using DSC-104 to treat patients with moderate to severe asthma.

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

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

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

WE WILL NEED ADDITIONAL CAPITAL AND OUR ABILITY TO CONTINUE ALL OF OUR EXISTING PLANNED RESEARCH AND DEVELOPMENT ACTIVITIES IS UNCERTAIN. ANY ADDITIONAL FINANCING COULD RESULT IN EQUITY DILUTION.

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

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge, the credit facility with PharmaBio and our capital equipment lease financing arrangement with 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. See "Risks Related to our Business - - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders".

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

OUR COMMITTED EQUITY FINANCING FACILITY MAY HAVE A DILUTIVE IMPACT ON OUR STOCKHOLDERS.

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

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

We may not be able to meet the conditions we are required to meet under CEFF and we may not be able to access any portion of the $75.0 million available under the CEFF.

THE CLINICAL TRIAL AND REGULATORY APPROVAL PROCESS FOR OUR PRODUCTS IS EXPENSIVE AND TIME CONSUMING, AND THE OUTCOME IS UNCERTAIN.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and comparable agencies in foreign countries that the manufacturer of the product maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. On April 14, 2004, we filed an NDA for Surfaxin as a prevention for RDS in premature infants which such filing was accepted by the FDA on June 15, 2004. The FDA established a target date of February 13, 2005, for completion of the review of such NDA. However, the FDA may not complete the review by such time or may reject the NDA.

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

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

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

The Committee for Orphan Medical Products of the EMEA has adopted a positive opinion recommending the granting of orphan medical product designations for Surfaxin in the prevention and treatment of RDS in premature infants. The EMEA has already granted us Orphan Medical Product designation for Surfaxin for indications of MAS in full-term infants and ALI in adults.

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

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

IN ORDER TO CONDUCT OUR CLINICAL TRIALS WE NEED ADEQUATE SUPPLIES OF OUR DRUG SUBSTANCE AND DRUG PRODUCT, WHICH MAY NOT BE READILY AVAILABLE.

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

IF THE PARTIES WE DEPEND ON FOR MANUFACTURING OUR PHARMACEUTICAL PRODUCTS DO NOT TIMELY SUPPLY THESE PRODUCTS, IT MAY DELAY OR IMPAIR OUR ABILITY TO DEVELOP AND MARKET OUR PRODUCTS.

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

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

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

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

OUR STRATEGY, IN MANY CASES, IS TO ENTER INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES WITH RESPECT TO OUR PRODUCTS AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PRODUCTS.

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

We have entered into an exclusive collaboration arrangement in the United States with Quintiles and PharmaBio to commercialize, sell and market Surfaxin in the United States for indications of RDS and MAS. As part of our collaboration with Quintiles, Quintiles is obligated to build a sales force solely dedicated to the sale of Surfaxin upon the approval of an NDA 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 has committed 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 $10.0 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 and its wholly owned subsidiary, Ortho Pharmaceutical Corporation, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES COULD LIMIT OUR ABILITY TO MARKET OUR PRODUCTS.

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

IF WE CANNOT MEET REQUIREMENTS UNDER OUR LICENSE AGREEMENTS, WE COULD LOSE THE RIGHTS TO OUR PRODUCTS.

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

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

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

WE RELY ON CONFIDENTIALITY AGREEMENTS THAT COULD BE BREACHED AND MAY BE DIFFICULT TO ENFORCE.

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

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

OUR LACK OF MARKETING AND SALES EXPERIENCE COULD LIMIT OUR ABILITY TO GENERATE REVENUES FROM FUTURE PRODUCT SALES.

We have limited marketing, sales, and distribution experience and a limited number of marketing and sales personnel. As a result, we will depend significantly on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of RDS in premature infants and MAS in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of RDS, MAS and ALI/ARDS 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 RDS in premature infants, MAS in full-term infants and ALI/ARDS in adult patients in the relevant territories depends, in part, on Quintiles', PharmaBio's and Esteve's performance of their contractual obligations. The failure of either party to do so may have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements with terms acceptable to us, if at all, 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 2004 through 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

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

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

OUR INDUSTRY IS HIGHLY COMPETITIVE AND WE HAVE LESS CAPITAL AND RESOURCES THAN MANY OF OUR COMPETITORS, WHICH MAY GIVE THEM AN ADVANTAGE IN DEVELOPING AND MARKETING PRODUCTS SIMILAR TO OURS OR MAKE OUR PRODUCTS OBSOLETE.

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

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

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

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

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Exosurf(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. This product, however, does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer. Curosurf(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 these indications that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered 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 $10.0 million per occurrence and $10. million in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

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

DIRECTORS, EXECUTIVE OFFICERS, PRINCIPAL STOCKHOLDERS AND AFFILIATED ENTITIES OWN A SIGNIFICANT PERCENTAGE OF OUR CAPITAL STOCK, AND THEY MAY MAKE DECISIONS THAT YOU DO NOT CONSIDER TO BE IN YOUR BEST INTEREST.

As of June 30, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

THE MARKET PRICE OF OUR STOCK MAY BE ADVERSELY AFFECTED BY MARKET VOLATILITY.

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

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

Our common stock is listed for quotation on the NASDAQ National Market. During the six-month period ended June 30, 2004, the price of our common stock has ranged from $8.25 to $13.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended June 30, 2004, the average daily trading volume in our common stock was approximately 517,000 shares and the average number of transactions per day was approximately 1,600. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the National Market. If the common stock were no longer listed on the National Market, investors might only be able to trade on the Nasdaq SmallCap Market, in the over-the-counter market in the Pink Sheets(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, 2004, we had 46,914,808 shares of common stock outstanding. In addition, as of June 30, 2004, up to approximately 7,918,238 shares of our common stock were issuable upon exercise of outstanding options and warrants. On December 19, 2003, we filed a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. Since the shelf registration statement was filed, we have sold 2,200,000 shares under the registration statement leaving 4,300,000 shares of our common stock available for us to sell in registered transactions under the shelf registration statement. We have no immediate plans to sell any securities under the shelf registration. However, subject to the effectiveness of the shelf registration statement, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time. See "Risks Related to our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

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

PROVISIONS OF OUR CERTIFICATE OF INCORPORATION, SHAREHOLDERS RIGHTS AGREEMENT AND DELAWARE LAW COULD DEFER A CHANGE OF OUR MANAGEMENT WHICH COULD DISCOURAGE OR DELAY OFFERS TO ACQUIRE US.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive and financial officers reviewed and evaluated our disclosure controls and procedures (as defined in Rule 13a-15 promulgated under the Securities Exchange Act of 1934) prior to the filing of this Quarterly Report. Based on that evaluation, 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 April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.8 million, respectively.

In the quarter ended June 30, 2004, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 820,499 shares of our common stock at various exercise prices ranging from $0.32 to $12.19 per share. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker-dealers were involved in the sale and no commissions were paid by us.

We have a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, we allowed for periodic discretionary matches of newly issued shares of common stock with the amount of any such match determined as a percentage of each participant's cash contribution. The total match for the quarter ended June 30, 2004 was approximately $51,000.

During the six months ended June 30, 2004, certain members of our management, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tendered shares of common stock then held by such members in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. For the six months ended June 30, 2004, 140,425 shares of our common stock were tendered to us by such parties in lieu of cash at an average price of $12.02 per share. These shares are accounted for as treasury stock.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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

At our annual meeting of the stockholders of the Company held on May 11, 2004, the following matters were voted on by the stockholders: (i) the election of five directors; (ii) the approval of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending December 31, 2004; (iii) consideration and approval of an amendment to our 1998 Amended and Restated Stock Incentive Plan to increase the number of shares of common stock available for issuance under the 1998 Amended and Restated Stock Incentive Plan by 3,000,000 shares; and (iv) consideration and approval of an amendment to our Restated Certificate of Incorporation to increase the number of shares of common stock available for issuance by 20,000,000. The results of such shareholder votes are as follows:

(i) Election of Directors

	For	Withheld
Robert J. Capetola, Ph.D.	31,742,129	1,196,068
Antonio Esteve, Ph.D.	31,785,177	1,153,020
Max Link, Ph.D.	30,341,431	2,596,766
Herbert H. McDade, Jr.	32,254,052	684,145
Marvin E. Rosenthale, Ph.D.	32,263,002	675,195

(ii) Approval of Independent Auditors

For	Against	Abstain
32,693,211	168,009	76,977

(iii) Amendment to the 1998 Amended and Restated Stock Incentive Plan

For	Against	Abstain
14,353,401	2,962,982	59,232

(iv) Amendment to our Restated Certificate of Incorporation

For	Against	Abstain
31,580,899	1,303,462	53,836

ITEM 5. OTHER INFORMATION.

SUBSEQUENT EVENTS

In July 2004, we entered into a CEFF with Kingsbridge pursuant to which Kingsbridge has committed to finance up to $75 million of capital to support our future growth. Subject to certain limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of our common stock. Subject to certain conditions and limitations, the CEFF allows us to raise capital as required, at the time, price and in amounts deemed suitable to us, during the three-year period following the effectiveness of the registration statement to be filed with the Commission in connection with the CEFF.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(A) EXHIBITS:

3.1 Amendment to the Certificate of Incorporation

31.1 Section 302 Certification of Chief Executive Officer

31.2 Section 302 Certification of Chief Financial Officer

32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer

(B) REPORTS ON FORM 8-K:

We filed three Current Reports on Form 8-K during the three months ended June 30, 2004. We filed a Current Report on May 10, 2004, reporting financial results for the quarter ended March 31, 2004 and providing selected updates on the Company's progress since the end of fiscal year 2003. We filed a Current Report on June 15, 2004, reporting the FDA's acceptance of the NDA filing for the use of Surfaxin in preventing RDS in premature infants. We filed a Current Report on June 30, 2004, reporting the approval for trading of our common stock on the NASDAQ National Market.

SIGNATURES, AND CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER AND THE CHIEF FINANCIAL OFFICER OF THE COMPANY.

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

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

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: August 9, 2004

/s/ Robert J. Capetola

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

Date: August 9, 2004

/s/ John G. Cooper

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

CERTIFICATE OF AMENDMENT
TO THE
CERTIFICATE OF INCORPORATION
OF
DISCOVERY LABORATORIES, INC.

Pursuant to Section 242
of the General Corporation Law
of the State of Delaware

Discovery Laboratories, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify as follows:

1. The name of the Corporation is Discovery Laboratories, Inc.

2. The fourth paragraph of the Restated Certificate of Incorporation of the Corporation, as heretofore amended, is amended to read in its entirety as follows:

"FOURTH: Authorization.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 85,000,000 consisting of 80,000,000 shares of common stock, par value $.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $.001 per share (the "Preferred Stock").

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance."

3. The foregoing amendment was duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Discovery Laboratories, Inc. has caused this Certificate of Amendment to be signed this 28th day of May, 2004.

DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola

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

CERTIFICATIONS

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

I, Robert J. Capetola, certify that:

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

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

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

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

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

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

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

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

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

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

Date: August 9, 2004

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

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

I, John G. Cooper, certify that:

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

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

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

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

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

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

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

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

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

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

Date: August 9, 2004

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

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

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

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

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

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

Date: August 9, 2004

Name: /s/ Robert J. Capetola

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

Name: /s/ John G. Cooper

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