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 March 31, 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). [ ] Yes [X] No

As of April 30, 2004, 46,738,213 shares of common stock, par value $.001 per share, were outstanding.

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PART II - OTHER INFORMATION

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

	MARCH 31, 2004	DECEMBER 31, 2003
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,564,000	$ 29,422,000
Note receivable - current	2,000	3,000
Prepaid expenses and other current assets	558,000	665,000
Total current assets	24,124,000	30,090,000
Property and equipment, net of accumulated depreciation	2,878,000	2,414,000
Note receivable, net of current portion	192,000	192,000
Other assets	19,000	19,000
Total Assets	$ 27,213,000	$ 32,715,000
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,362,000	$ 4,210,000
Credit facility with corporate partner	3,265,000	2,436,000
Capitalized lease - current portion	447,000	383,000
Total current liabilities	8,074,000	7,029,000
Deferred revenue	538,000	672,000
Capitalized lease, net of current portion	833,000	711,000
Total Liabilities	9,445,000	8,412,000
Stockholders' equity:		
Common stock, $.001 par value; 60,000,000 authorized; 43,914,649 and 42,491,438 issued and outstanding at March 31, 2004 and December 31, 2003, respectively	44,000	43,000
Additional paid-in capital	126,176,000	122,409,000
Unearned portion of compensatory stock options	--	(2,000)
Accumulated deficit	(105,730,000)	(96,858,000)
Treasury stock (at cost; 282,902 and 167,179 shares at March 31, 2004 and December 31, 2003, respectively)	(2,722,000)	(1,289,000)
Total stockholders' equity	17,768,000	24,303,000
Total Liabilities & Stockholders' Equity	$ 27,213,000	$ 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 MARCH 31,	
	2004	2003
Revenues:		
Contracts, Licensing, Grants & Milestones	$ 142,000	$ 393,000
Expenses:		
Research & Development	6,710,000	3,844,000
General & Administrative	2,281,000	1,167,000
Total Expenses	8,991,000	5,011,000
Operating Loss	(8,849,000)	(4,618,000)
Other income and expenses:		
Interest income, dividends, realized gains, and other income	63,000	169,000
Interest expense	(86,000)	(56,000)
Net Loss	$ (8,872,000)	$ (4,505,000)
Net loss per common share - basic and diluted	$ (0.20)	$ (0.14)
Weighted average number of common shares outstanding - basic and diluted	43,320,268	32,856,526

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Three Months Ended March 31,	
	2004	2003
Cash flows from operating activities:		
Net loss	$ (8,872,000)	$ (4,505,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	116,000	86,000
Realized gains on marketable securities	--	(42,000)
Compensatory stock options	53,000	(1,000)
Changes in:		
Prepaid expenses and other current assets	81,000	68,000
Accounts payable and accrued expenses	152,000	(446,000)
Other assets	--	(2,000)
Amortization of deferred revenue	(134,000)	(180,000)
Net cash used in operating activities	(8,604,000)	(5,022,000)
Cash Flows from investing activities:		
Purchase of property and equipment	(301,000)	(61,000)
Related party loan payments received	1,000	1,000
Purchase of marketable securities	--	(133,000)
Proceeds from sale or maturity of marketable securities	--	3,478,000
Net cash (used in) provided by investing activities	(300,000)	3,285,000
Cash Flows from financing activities:		
Proceeds from issuance of securities, net of expenses	2,310,000	(66,000)
Proceeds from credit facility	829,000	198,000
Principal payments under capital lease obligation	(93,000)	(49,000)
Net cash provided by financing activities	3,046,000	83,000
Net decrease in cash and cash equivalents	(5,858,000)	(1,654,000)
Cash and cash equivalents - beginning of period	29,422,000	8,538,000
Cash and cash equivalents - end of period	$ 23,564,000	$ 6,884,000
Supplementary disclosure of cash flows information:		
Interest paid	$ 70,000	$ 13,000
Noncash transactions:		
Class H warrants revalued	(26,000)	--
Equipment acquired through capitalized lease	279,000	190,000
Unrealized loss on marketable securities	--	(63,000)
Exchange of common stock for exercise of stock options	1,433,000	--

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 its 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.

Discovery has filed a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) for clearance to market Surfaxin(R), Discovery's lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Our Surfactant Replacement Therapy is also in a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome in adults, as well as in a Phase 3 and Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. In addition, we recently completed a successful Phase 1b clinical trial in healthy volunteers and mild asthmatics and are currently preparing to initiate a Phase 2 clinical trial evaluating the safety, tolerability and efficacy of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.

Presently, we are evaluating the development of other aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units in hospitals that are suffering from Respiratory Dysfunction. We are also evaluating aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), rhinitis, sinusitis (infection of the sinuses), sleep apnea and otitis media (inner ear infection).

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 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, recognizes 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.

Had compensation cost for the our stock option plans been determined based upon the fair value of the options at the grant date of awards under the plans consistent with the methodology prescribed under SFAS No. 148, the pro forma net loss for the periods ended March 31, 2004 and 2003 would have been as follows:

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Net loss as reported	$(8,872,000)	$(4,505,000)
Additional stock-based employee compensation	$ --	$ (315,000)
Pro forma net loss	$(8,872,000)	$(4,820,000)
Pro forma net loss per share	$ (0.20)	$ (0.15)

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-month period ended March 31, 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 $8,872,000 for the three months ended March 31, 2004, and approximately $4,568,000 for the three months ended March 31, 2003.

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 March 31, 2004 and December 31, 2003 was approximately $194,000 and $195,000, respectively.

NOTE 5 - TREASURY STOCK

During the three months ended March 31, 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 three months ended March 31, 2004, 115,723 shares of our common stock were tendered to us by such parties in lieu of cash at an average price of $12.38 per share. These shares are accounted for as treasury stock. See Part II, Item 2. Changes in Securities and Use of Proceeds.

NOTE 6 - SUBSEQUENT EVENTS

Filing of New Drug Application (NDA)

In April 2004, we submitted an NDA to the FDA for clearance to market Surfaxin(R) for the prevention of RDS in premature infants. Surfaxin is a novel, peptide-containing, humanized lung surfactant developed from Discovery's proprietary Surfactant Replacement Technology platform.

The NDA filing is supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The principal trial was a landmark, 1,294 patient pivotal study that demonstrated Surfaxin's superiority to Exosurf(R), a non-protein containing synthetic surfactant. In this pivotal trial, another surfactant, Survanta(R), which is derived from cows and is the leading surfactant used in the United States, served as a reference arm. The second trial was a 252 patient supportive study that demonstrated Surfaxin's non-inferiority to Curosurf(R), a pig-derived surfactant and the leading surfactant used in Europe.

Equity Financing

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

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 March 31, 2004, we had an accumulated deficit of approximately $106 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 and related expenses. 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 March 31, 2004, we had cash and investments of approximately $23.6 million, a $8.5 million secured revolving credit facility with PharmaBio Development, Inc., of which $5.7 million was available for borrowing and $3.3 million was outstanding, and a $4 million capital equipment lease financing arrangement, of which approximately $2.6 million was available for borrowing and $1.4 million had been used.

In April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.7 million, respectively. 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 recently completed two Phase 3 clinical trials of Surfaxin for the treatment of Respiratory Distress Syndrome 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 Acute Respiratory Distress Syndrome in adults, 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 enrollment for this trial in the second half 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 tolerability and lung deposition of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma and are currently preparing to initiate a Phase 2 clinical trial in the second half of 2004. We are evaluating the development of aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units suffering from Respiratory Dysfunction and are preparing to initiate a clinical trial in the second half of 2004. 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"; - "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 Respiratory Distress Syndrome 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.

In October 2003, we entered into a Technology Transfer and Manufacturing Agreement with a contract manufacturer, Laureate Pharma, L.P., which provides for the establishment of a Surfaxin manufacturing line together with the production of clinical and commercial drug supply in conformance with current

Good Manufacturing Practices (cGMP). This agreement also encompasses plans for manufacturing scale-up and enhancements, including additional equipment to support our anticipated commercial-scale requirements of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and our anticipated clinical-scale production requirements of Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults. In addition to our arrangement with Laureate, we plan to conduct other activities in connection with the implementation of our long term manufacturing strategy including evaluating and establishing additional contract or Discovery-owned manufacturing facilities. See "Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitors' drug product, which may not be readily available"; and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

We have a collaboration arrangement with Quintiles Transnational Corp., and its affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. Quintiles 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 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 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 treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. Our exclusive supply agreement with Esteve provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve will pay certain clinical trial costs related to obtaining regulatory approval in Europe for the indications of Acute Lung Injury/Acute Respiratory Distress Syndrome 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 March 31, 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 months ended March 31, 2004 was $8,872,000 ($0.20 per common share). Net loss for the three months ended March 31, 2003 was $4,505,000 ($0.14 per common share).

Revenues

Revenues from research and development collaborative agreements and grants for the three months ended March 31, 2004 and 2003 were $142,000 and $393,000, respectively. These revenues are associated with our research and development collaborative arrangements, primarily our alliance with Esteve to develop, market and sell Surfaxin throughout Europe and Latin America and a Small Business Innovative Research (SBIR) grant to develop Surfaxin for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. The decrease in the three months ending March 31, 2004 reflects: (i) the conclusion, in 2003, of work activities for our Small Business Innovative Research (SBIR) grant for research for treatments of Acute Lung Injury/Acute Respiratory Distress Syndrome in adults; and (ii) the extension of the amortization period and related revenue recognition of the funding previously provided to us in connection with our strategic alliance with Esteve.

Expenses

Research and development expenses for the three months ended March 31, 2004 and 2003 were $6,710,000 and $3,844,000, respectively, an increase of $2,866,000. Included in research and development expenses for the three months ended March 31, 2004 was $1.4 million for manufacturing activities to support the production of clinical and commercial drug supply of Surfaxin at Laureate's facility in conformance with current Good Manufacturing Practices (cGMPs). The increase in research and development expenses versus last year also reflects costs incurred for (i) the development and regulatory efforts to complete two Phase 3 clinical trials for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, preparation of a New Drug Application that was filed with the FDA in April 2004, and continuation of the six and twelve month clinical follow-up on all enrolled patients; (ii) activities in support of development of our surfactant replacement therapy pipeline, including DSC-104 to potentially treat patients with asthma (where we are currently preparing to initiate a Phase 2 clinical trial in the second half of 2004), and aerosolized formulations of our humanized surfactant to potentially treat premature infants in Neonatal Intensive Care Units suffering from Respiratory Dysfunction (where we are preparing to initiate a clinical trial in the second half of 2004); and (iii) the Phase 2 clinical trial for Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults.

General and administrative expenses for the three months ended March 31, 2004 and 2003 were $2,281,000 and $1,167,000, respectively, an increase of $1,114,000. 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. Included in general and administrative costs was approximately $936,000 and $200,000 for the three months ended March 31, 2004 and 2003, respectively, related to pre-launch commercialization activities for Surfaxin, of which $829,000 and $200,000, respectively, were attributable to activities conducted in connection with a collaboration agreement with Quintiles (for which funding is provided by the secured, revolving credit facility with PharmaBio, discussed below in "Liquidity and Capital Resources"). The increase in general and administrative expenses versus the same period last year also reflects costs incurred primarily to support corporate governance initiatives in compliance with the Sarbanes-Oxley Act, legal activities related to the preparation and filing of patents in connection with the expansion of our Surfactant Replacement Therapy pipeline, and commercialization activities in preparation for potential approval and launch of Surfaxin for RDS.

Other Income and Expense

Other income and expense (net) for the three months ended March 31, 2004 and 2003 was ($23,000) and $113,000, respectively. Interest income for the three months ended March 31, 2004 and 2003 was $63,000 and $169,000. The decrease is primarily due to a reduction in interest earned on our cash and cash equivalents primarily due to a general reduction in market interest rates. Interest expense for the three months ended March 31, 2004 and 2003 was $86,000 and $56,000, respectively. The increase is due to interest expense associated with our secured, revolving credit facility and capital lease financing arrangements. See "Liquidity and Capital Resources."

LIQUIDITY AND CAPITAL RESOURCES

Cash and Cash Equivalents

As of March 31, 2004, we had cash and cash equivalents of approximately $23.6 million as compared to approximately $29.4 million as of December 31, 2003. As of March 31, 2004, we had working capital of approximately $16.1 million as compared to the working capital of approximately $23.1 million as of December 31, 2003. The decrease in working capital of $7 million from the previous quarter is primarily due to: (i) $8.6 million of cash used in operations; (ii) $2.4 million received from the exercise of outstanding options and warrants; and (iii) $1.1 million from our secured, revolving credit facility and capital lease financing arrangements. Also, in April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.7 million, respectively.

Secured, Revolving Credit Facility and Capital Lease Financing Arrangements

We have a secured revolving credit facility of up to $8.5 million to $10 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004,

and monies become available in three tranches upon satisfying certain conditions. We have satisfied the conditions for availability of the first two tranches and at March 31, 2004, the amount available under the credit facility was approximately $5.7 million, of which $3.3 million, was outstanding. Interest on amounts advanced under the 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 not likely unless the FDA expedites the review of the NDA for Surfaxin for the treatment of Respiratory Distress Syndrome 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 million. As of March 31, 2004, approximately $1.4 million had been used under this financing arrangement.

Working Capital

With our capital resources as of March 31, 2004 and the net proceeds from our April financing, we believe our current working capital is sufficient to meet our planned research and development and operational activities into 2005. 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 April 2004, we completed an underwritten public offering of 2,200,000 shares of common stock. The shares were priced at $11.00 per share resulting in our receipt of gross and net proceeds equal to $24.2 million and approximately $22.7 million, respectively.

In 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 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. The vested portion of the Class H warrants were cashlessly exercised resulting in the issuance of 160,318 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 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 three months ended March 31, 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 three months ended March 31, 2004, 115,723 shares of our common stock were tendered to us by such parties in lieu of cash at an average price of $12.38 per share. These shares are accounted for as treasury stock.

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 March 31, 2004, we have an accumulated deficit of approximately $105,730,000, 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 for surfactant replacement therapy to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently we completed and announced top-line results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the treatment of Respiratory Distress Syndrome in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of Acute Respiratory Distress syndrome in adults and a Phase 3 and a Phase 2 clinical trial for the treatment of Meconium Aspiration Syndrome 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.

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

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

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

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

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available financial resources will be adequate to satisfy our capital needs into 2005. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others.

We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

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

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

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

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish 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 approve an NDA filed by a pharmaceutical or biotechnology company for such drug product.

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, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as "fast-track" products under provisions of the Food and Drug Administration Modernization Act of 1997. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: Acute Respiratory Distress Syndrome in adults; Respiratory Distress Syndrome in infants; and Meconium Aspiration Syndrome in full-term infants. To support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years. Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

In April 2004, we submitted an NDA to the FDA for clearance to market Surfaxin for the prevention of RDS in premature infants. The FDA may not complete its review in a timely manner. In addition, the FDA may request further data or disapprove the NDA. If Surfaxin is not approved by the FDA for the prevention of RDS in premature infants, if the review time is substantially prolonged or if the FDA requires further clinical studies prior to approval, we have no short-term alternative for generating substantial revenue or income. Surfaxin may not be approved for the prevention of RDS because the FDA may find our efficacy and safety data deficient or for other reasons. 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 AND, FREQUENTLY, COMPETITORS' DRUG PRODUCT, WHICH MAY NOT BE READILY AVAILABLE.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. We transferred our manufacturing capabilities from our single validated clinical manufacturing facility, owned and operated by Akorn, Inc., to a new contract manufacturer, Laureate Pharma L.P., and we are currently producing appropriate clinical grade material of our drug substance that meets the standards for use in our ongoing clinical studies. In the future, Laureate 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 substance for use in our ongoing clinical studies.

Laureate or other outside manufacturers may not be able to (i) produce our drug substance to appropriate standards for use in clinical studies, (ii) perform under 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 or manufacturing department and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with 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 treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin in Europe for the indications of Acute Lung Injury/Acute Respiratory Distress Syndrome. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency 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 Respiratory Distress Syndrome and Meconium Aspiration Syndrome. 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 a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio 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 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 our products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to Our Business - Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, OTHER COMPANIES COULD USE OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OTHER COMPANIES COULD PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS.

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

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

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark

Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

EVEN IF WE OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE SUFFICIENTLY BROAD AND OTHERS COULD COMPETE WITH US.

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

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson Inc. and Ortho Pharmaceutical Corporation which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to Our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

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

parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

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

We depend on licensing 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 do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe and Latin America. See "Risks Related to Our Business - - Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles', PharmaBio's and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements 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 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 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 March 31, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 14% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

- --announcements of the results of clinical trials by us or our competitors;
- --adverse reactions to products;
- --governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- --changes in the United States or foreign regulatory policy during the period of product development;
- --developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- --announcements of technological innovations by us or our competitors;
- --announcements of new products or new contracts by us or our competitors;

- --actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- --changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- --conditions and trends in the pharmaceutical and other industries;
- --new accounting standards; and
- --the occurrence of any of the risks described in this "Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the three month period ended March 31, 2004, the price of our common stock has ranged from $9.94 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 three month period ended March 31, 2004, the average daily trading volume in our common stock was approximately 598,000 shares and the average number of transactions per day was approximately 1,800. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

A SUBSTANTIAL NUMBER OF OUR SECURITIES ARE ELIGIBLE FOR FUTURE SALE AND THIS COULD AFFECT THE MARKET PRICE FOR OUR STOCK AND OUR ABILITY TO RAISE CAPITAL.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of March 31, 2004, we had 43,914,649 shares of common stock outstanding. In addition, as of March 31, 2004, up to approximately 6,889,600 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 6.5 million shares of common stock. In April 2004, we completed an underwritten public offering of 2.2 million shares of common stock related to the shelf registration statement. We have no immediate plans to sell the remaining securities under the

shelf registration. However, as the registration statement has been declared effective by the Commission, 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.

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 Certificate of Incorporation, 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 Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. Our Shareholders Rights Agreement significantly impairs the ability of third parties, under certain circumstances, 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.

Effective February 6, 2004, our Board of Directors declared a dividend of one preferred stock purchase right for each share of our common stock to be issued to stockholders of record as of that date. Each share of common stock that we issue after such date through the expiration date of the Shareholders Rights Agreement shall be issued with a tandem right. Each Right represents the right to purchase one ten-thousandth of a share of our Series A Junior Participating Cumulative Preferred Stock at an exercise price equal to $50 per right. A summary of the principal terms of the Shareholders Rights Agreement is set forth in our Current Report on Form 8-K and our Registration Statement on Form 8-A, each as filed with the Commission on February 6, 2004.

In the quarter ended March 31, 2004, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 1,534,797 shares of our common stock at various exercise prices ranging from $0.51 per share to $12.75 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 Company Stock with the amount of any such match determined as a percentage of each participant's cash contribution. The total match for the three months ended March 31, 2004 was $34,000.

During the three months ended March 31, 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 three months ended March 31, 2004, 115,723 shares of our common stock were tendered to us by such parties in lieu of cash at an average price of $12.38 per share. These shares are accounted for as treasury stock. The following table sets forth information regarding our receipt of shares of our common stock on a monthly basis during the first quarter of fiscal year 2004:

	Number of shares received in lieu of cash for the exercise of stock options	Average price per share
January 2004	97,226	12.44
February 2004	--	--
March 2004	18,497	12.08
Total	115,723	12.38

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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

None.

ITEM 5. OTHER INFORMATION.

SUBSEQUENT EVENTS

Filing of New Drug Application (NDA)

In April 2004, we submitted an NDA to the FDA for clearance to market Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.

The NDA filing is supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The principal trial was a landmark, 1,294 patient pivotal study that demonstrated Surfaxin's superiority to Exosurf, a non-protein containing synthetic surfactant. In this pivotal trial, another surfactant, Survanta, which is derived from cows and is the leading surfactant used in the United States, served as a reference arm. The second trial was a 252 patient supportive study that demonstrated Surfaxin's non-inferiority to Curosurf, a pig-derived surfactant and the leading surfactant used in Europe.

On May 2, 2004 we presented detailed results from the Surfaxin Phase 3 clinical trials at the 2004 annual meeting of the Pediatric Academic Society (PAS) in San Francisco.

Equity Financing

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

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

(A) EXHIBITS:

31.1	Section 302 Certification of Chief Executive Officer
31.2	Section 302 Certification of Chief Financial Officer
32.1	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 March 31, 2004. We filed a Current Report on February 6, 2004, reporting that our Board of Directors had adopted a shareholder rights plan under which all shareholders of record as of February 6, 2004, will receive rights to purchase shares of a new series of preferred stock. We filed a Current Report on February 19, 2004, reporting that a conference call would take place to provide an overview of the secondary endpoints from certain safety results from our two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants as well as an update on manufacturing. We filed a Current Report on March 30, 2004, reporting the initiation of an underwritten public offering of 2,200,000 shares of our common stock at a price of $11.00 per share.

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: May 7, 2004

/s/ Robert J. Capetola

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

Date: May 7, 2004

/s/ John G. Cooper

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

Exhibit 31.1

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 (the "Evaluation Date"); 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 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: May 7, 2004

/s/ Robert J. Capetola

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

Exhibit 31.2

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 (the "Evaluation Date"); 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 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: May 7, 2004

/s/ John G. Cooper

John G. Cooper
Executive Vice President and
Chief Financial Officer

Exhibit 32.1

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 March 31, 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: May 7, 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