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 September 30, 2006

or

o **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 Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976-3622
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non -accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

As of November 6, 2006, 64,273,681 shares of the registrant's common stock, par value $0.001 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., and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "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. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. The forward-looking statements include all matters that are not historical facts and include, without limitation: statements concerning our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; plans to seek collaboration arrangements and strategic alliances with pharmaceutical companies or others to develop, manufacture and market products; the research and development of particular compounds and technologies; the period of time for which our existing resources will enable us to fund our operations; and anticipated cost savings and accounting charges arising out of our recent workforce reductions and corporate restructuring.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 risk that financial conditions may change;
- risks relating to the progress of our research and development;
- the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies);
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities will not approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product;
- risks that the FDA or other regulatory authorities may delay consideration of any applications that we file;
- risks relating to the ability of our third party materials, drug substance and device suppliers and development partners to provide us with adequate supplies of materials, drug substance and devices to support manufacture of drug product for initiation and completion of any of our clinical studies;
- risks relating to our drug manufacturing operations;
- risks relating to the integration of our manufacturing operations into our existing operations;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies;
- risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements;
- the risk that we or our marketing partners will not succeed in developing market awareness of our products;
- the risk that we or our marketing partners will not be able to attract or maintain qualified personnel;
- risks relating to the development of competing therapies and/or technologies by other companies;
- risks relating to our recent workforce reductions and corporate restructuring:
- risks relating to the impact of litigation that has been and may be brought against the Company and its officers and directors; and
- other risks and uncertainties detailed in Part II, Item 1A: Risk Factors and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2005, and those described from time to time in our future reports filed with the Securities and Exchange Commission (SEC).

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
Consolidated Balance Sheets
(in thousands, except per share data)

	September 30, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 18,893	$ 47,010
Restricted cash	830	647
Available-for-sale marketable securities	–	3,251
Prepaid expenses and other current assets	278	560
Total Current Assets	20,001	51,468
Property and equipment, net of accumulated depreciation	4,604	4,322
Other assets	216	218
Total Assets	$ 24,821	$ 56,008
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 6,867	$ 7,540
Credit facility, current portion	8,500	8,500
Capitalized leases and note payable, current portion	1,922	1,568
Total Current Liabilities	17,289	17,608
Capitalized leases and note payable, non-current portion	2,867	3,323
Other liabilities	622	239
Total Liabilities	20,778	21,170
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized; 62,725 and 61,335 shares issued, and 62,374 and 61,022 shares outstanding at September 30, 2006 and December 31, 2005, respectively.	63	61
Additional paid-in capital	247,648	240,028
Unearned portion of compensatory stock options	(58)	(230)
Accumulated deficit	(240,453)	(201,965)
Treasury stock (at cost); 351 and 313 shares at September 30, 2006 and December 31, 2005, respectively.	(3,157)	(3,054)
Accumulated other comprehensive loss	—	(2)
Total Stockholders' Equity	4,043	34,838
Total Liabilities & Stockholders' Equity	$ 24,821	$ 56,008

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	**2005**	**2006**	**2005**
Revenues:				
Contracts and Grants	$ -	$ 20	$ -	$ 105
Expenses:				
Research & Development	5,204	5,676	18,728	16,660
General & Administrative	2,723	4,817	15,429	13,182
Restructuring Charge	-	-	4,805	-
Total Operating Expenses	7,927	10,493	38,962	29,842
Operating Loss	(7,927)	(10,473)	(38,962)	(29,737)
Other income / (expense):				
Interest and other income	291	328	1,468	884
Interest expense	(362)	(261)	(994)	(695)
Other income / (expense), net	(71)	67	474	189
Net Loss	$ (7,998)	$ (10,406)	$ (38,488)	$ (29,548)
Net loss per common share - Basic and diluted	$ (0.13)	$ (0.19)	$ (0.62)	$ (0.56)
Weighted average number of common shares outstanding - basic and diluted	62,312	54,476	61,703	52,844

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2006	**2005**
Cash flows from operating activities:		
Net loss	$ (38,488)	$ (29,548)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	685	585
Stock-based compensation expense / 401(k) match	4,891	468
Loss on disposal of property and equipment	—	16
Changes in:		
Prepaid expenses and other current assets	282	(35)
Accounts payable and accrued expenses	(673)	(1,100)
Other assets	2	13
Other liabilities	383	(105)
Net cash used in operating activities	(32,918)	(29,706)
Cash flows from investing activities:		
Purchase of property and equipment	(967)	(667)
Restricted cash	(183)	(1)
Purchases of marketable securities	(4,631)	(30,110)
Proceeds from sales or maturity of marketable securities	7,884	24,408
Net cash provided by / (used in) investing activities	2,103	(6,370)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	2,903	45,402
Proceeds from credit facility	—	2,571
Equipment financed through capital lease obligation	1,130	757
Principal payments under capital lease obligation	(1,232)	(669)
Purchase of treasury stock	(103)	—
Net cash provided by financing activities	2,698	48,061
Net increase / (decrease) in cash and cash equivalents	(28,117)	11,985
Cash and cash equivalents – beginning of period	47,010	29,264
Cash and cash equivalents - end of period	$ 18,893	$ 41,249
Supplementary disclosure of cash flows information:		
Interest paid	$ 964	$ 612
Non-cash transactions:		
Unrealized gain/(loss) on marketable securities	2	(2)

See notes to consolidated financial statements

Notes to Consolidated Financial Statements (unaudited)

Note 1 – The Company and Basis of Presentation

The Company

Discovery Laboratories, Inc. (the Company) is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory disorders. Surfactants are produced naturally in the lungs and are essential for breathing. The Company's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. The Company believes that through this technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit (NICU), critical care unit and other hospital settings, to treat conditions for which there are few or no approved therapies available.

The Company's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. The Company's lead product is Surfaxin® (lucinactant). The Company has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and has received two Approvable Letters from the FDA in connection with this NDA. In addition, the Company recently announced preliminary results for its Phase 2 clinical trial investigating the use of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. The Company is also developing Aerosurf™, its proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), for the prevention and treatment of infants at risk for respiratory failure. The Company is preparing to initiate Phase 2 clinical studies with Aerosurf, potentially obviating the need for endotracheal intubation and conventional mechanical ventilation.

As part of the Company's ongoing efforts to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, the Company believes that its SRT will also potentially address Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), cystic fibrosis and other respiratory conditions.

The Company is implementing a business strategy that includes: (i) undertaking actions intended to gain regulatory approvals for Surfaxin for the prevention of RDS in premature infants in the United States, including (A) preparing to attend a meeting with the FDA in December 2006, with respect to which, in September 2006, we submitted an information package to the FDA addressing questions raised in the second Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA, (B) preparing our response to the second Approvable Letter, and (C) completing analysis and remediation of recent manufacturing issues (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations"); (ii) investing in development of SRT pipeline programs, including Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in our quality systems and our manufacturing capabilities at our manufacturing facility in Totowa, New Jersey that was acquired by the Company in December 2005 to produce surfactant drug products to meet anticipated clinical and commercial requirements of Surfaxin (if approved) as well as pre-clinical, clinical and future commercial needs of the Company's SRT product candidates (if approved) and, potentially, investing in additional facilities to be built or acquired by the Company in the future; and (iv) seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of the Company's SRT product candidates.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine month period ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

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

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

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109," (FIN 48). FIN 48 prescribes a
recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. The company does not believe that the adoption of FIN 48 will have a material impact on their financial statements.

Note 2 – Working Capital

Cash is required to fund the Company's working capital needs, to purchase capital assets, and to pay debt service, including principal and interest payments. The Company does not currently have any source of operating revenue and will require significant amounts of cash to continue to fund operations, clinical trials and research and development efforts until such time, if ever, that one of the Company's products receives regulatory approval for marketing and begins to generate sales. Since the Company has not generated any revenue from the sale of any products, the Company has primarily relied upon the capital markets and debt financings as its primary sources of funding. The Company will continue to be opportunistic in accessing the capital markets to obtain financing on terms satisfactory to the Company. The Company plans to fund its future cash requirements through:

- the issuance of equity and debt financings;
- payments from potential strategic collaborators, including license fees and sponsored research funding;
- sales of Surfaxin, if approved;
- sales of the Company's other product candidates, if approved;
- capital lease financings; and
- interest earned on invested capital.

Receipt of a second Approvable Letter and the occurrence of manufacturing issues in April 2006 (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations") caused the Company to modify its expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin. The related decline in the market value of the Company's common stock has made it more difficult to obtain equity and debt financing on terms that would be beneficial to the Company in the long term. In June 2006, the Company engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist the Company in identifying and evaluating strategic alternatives intended to enhance the future growth potential of the Company's SRT pipeline and maximize shareholder value. The Company is evaluating multiple strategic alternatives including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities. No assurances can be given that this evaluation will lead to any specific action or transaction.

After taking into account the recently implemented cost containment measures and the restructuring of the Company's credit facility with PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), an investment group of Quintiles Transnational Corp. (discussed in"Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources"), and before taking into account any strategic alternatives, potential financings or amounts that may be potentially available through the new Committed Equity Financing Facility (CEFF) entered into with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in April 2006 (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources"), the Company believes that its current working capital is sufficient to meet planned activities into mid-2007. Use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of common stock that may be issued by the Company under the CEFF (approximately 10.6 million shares were available for issuance under the CEFF as of September 30, 2006). In addition, during the eight trading day pricing period for a draw down, if the volume weighted average price of the Company's common stock (VWAP) for any one trading day is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of the Company's common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount that the Company had initially specified. (Also, see discussion in Subsequent Events, Note 10) The Company anticipates using the CEFF, when available, to support working capital needs in 2006 and 2007.

Note 3 – Net Loss Per Share

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

Note 4 – Stock-Based Employee Compensation

The Company has a stock-based employee compensation plan. Prior to January 1, 2006, the Company accounted for this plan under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, (Opinion 25) and related interpretations, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Generally, no stock-based employee compensation cost was recognized in the statements of operations, as options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of the grant. Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized in the three and nine months ended September 30, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair market value estimated in accordance with the original provisions of Statement 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based upon the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Results from prior periods have not been restated.

As a result of adopting Statement 123(R) on January 1, 2006, the Company's net loss for the three and nine months ended September 30, 2006 was $0.9 million (or $0.02 per share) and $4.1 million (or $0.06 per share), respectively, higher than if it had continued to account for share-based compensation under Opinion 25. For the three and nine months ended September 30, 2006, $0.3 million and $1.2 million of compensation expense was classified as research and development and $0.6 million and $2.9 million of compensation expense was classified as general and administrative.

For comparative purposes, the following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement 123(R) to options granted under the Company's stock option plan for the three and nine months ended September 30, 2005. For purposes of this pro forma disclosure, the value of the option is estimated using a Black-Scholes-Merton option-pricing formula that uses the September 30, 2005 assumptions set forth under "Stock Incentive Plan" below and amortized to expense over the options' vesting periods.

(in thousands, except per share data)	**Three Months Ended September 30, 2005**	**Nine Months Ended September 30, 2005**
Net loss, as reported	$ (10,406)	$ (29,548)
Net loss per share, as reported	$ (0.19)	$ (0.56)
Add: Stock-based employee compensation expense included in reported net loss	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,163)	(5,796)
Pro forma net loss	$ (11,569)	$ (35,344)
Pro forma net loss per share	$ (0.21)	$ (0.67)

Stock Incentive Plan

The Company's 1998 Stock Incentive Plan (the Plan) is shareholder-approved and currently allows for the grant of stock options and shares of our common stock to its eligible employees, officers, consultants, independent advisors and non-employee directors for up to 11,207,000 shares of our common stock. At September 30, options to purchase 9,554,000 shares were outstanding, and 1,653,000 shares remain available for issuance under the Plan. The Company believes that such awards better align the interests of its eligible participants with those of its shareholders. Option awards are granted with an exercise price equal to or greater than the closing sale price per share of the Company's common stock on the Nasdaq Global Market on the option grant date. Although the terms of any award vary, option awards generally vest based upon three years of continuous service and have 10-year contractual terms.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the Company's historical volatility and other factors. The Company also uses historical data and other factors to estimate option exercises and employee terminations within the valuation model. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

	September 30, 2006	September 30, 2005
Expected volatility	101%	77%
Expected term	5 years	3.5 years
Risk-free rate	5.0%	4.1%
Expected dividends	--	--

A summary of option activity under the Plan as of September 30, 2006 and changes during the period is presented below:

(in thousands, except for weighted-average data)

Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	8,440	$ 6.28		
Granted	904	7.08		
Exercised	(8)	3.15		
Forfeited or expired	(60)	6.97		
Outstanding at March 31, 2006	9,276	$ 6.35	7.3	$ 15,050
Vested at March 31, 2006	6,769	$ 6.63	6.9	$ 10,650
Exercisable at March 31, 2006	7,548	$ 6.23	6.8	$ 14,199

Outstanding at March 31, 2006	9,276	$ 6.35			
Granted	1,664	2.20			
Exercised	(2)	1.53			
Forfeited or expired	(1,140)	7.69			
Outstanding at June 30, 2006	9,798	$ 5.50	7.4	$	476
Vested at June 30, 2006	6,898	$ 6.13	6.8	$	360
Exercisable at June 30, 2006	7,491	$ 5.86	6.8	$	360
Outstanding at June 30, 2006	9,798	$ 5.50			
Granted	355	1.82			
Exercised	(25)	0.47			
Forfeited or expired	(574)	$ 8.10			
Outstanding at September 30, 2006	9,554	$ 5.22	7.3	$	584
Vested at September 30, 2006	6,456	$ 5.92	6.5	$	377
Exercisable at September 30, 2006	7,048	$ 5.65	6.5	$	377

Based upon application of the Black-Scholes-Merton option-pricing formula described above, the weighted-average grant-date fair value of options granted during the nine months ended September 30, 2006 was $2.54. The total intrinsic value of options exercised during the nine months ended September 30, 2006 was $79,000.

A summary of the status of the Company's nonvested shares issuable upon exercise of outstanding options and changes during the three and nine month periods are presented below:

(in thousands, except for weighted-average data)

	Option Shares	Weighted-Average Grant-Date Fair Value
Nonvested at January 1, 2006	1,907	$ 3.68
Granted	904	4.70
Vested	(252)	4.55
Forfeited	(53)	5.15
Nonvested at March 31, 2006	2,506	$ 3.89
Granted	1,664	1.68
Vested	(910)	2.00
Forfeited	(360)	4.61
Nonvested at June 30, 2006	2,900	$ 2.08
Granted	355	1.37
Vested	(125)	2.56
Forfeited	(32)	3.26
Nonvested at September 30, 2006	3,098	$ 2.66

As of September 30, 2006, there was $6.3 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.11 years.

Note 5 – Comprehensive Loss

Total comprehensive loss was $8.0 million and $38.5 million for the three months and nine months ended September 30, 2006, respectively, and $10.4 million and $29.6 and for the three and nine months ended September 30, 2005. Total comprehensive loss consists of the net loss and unrealized gains and losses on marketable securities.

Note 6 – Restricted Cash

There are cash balances that are restricted as to use and the Company discloses such amounts separately on the Company's balance sheets. There are two primary components of Restricted Cash: (a) a cash security deposit in the amount of $600,000 securing a letter of credit in the same amount related to the Company's lease agreement dated May 26, 2004 for office space in Warrington, Pennsylvania, and (b) a cash security deposit in the amount of approximately $175,500 securing a letter of credit in the same amount issued to support two "Bond to Discharge Lien" filed in Passaic County, New Jersey, in connection with an ongoing contractor dispute arising out of work done at the Company's manufacturing facility in Totowa, New Jersey. Beginning in March 2008, the security deposit and the letter of credit related to the lease agreement will be reduced to $400,000 and will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease in November 2009, the letter of credit will expire. Both letters of credit are secured by cash and are recorded in the Company's balance sheets as "Restricted Cash."

Note 7 – Q2 2006 Restructuring Charge

In April 2006, the Company reduced its staff levels and reorganized corporate management to lower the Company's cost structure and re-align its operations with changed business priorities. These actions were taken in response to the Company's revised expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants following the April 2006 Surfaxin process validation stability failure.

The reduction in workforce totaled 52 employees, representing approximately 33% of the Company's workforce, and was focused primarily on the Company's commercial infrastructure, the development of which is no longer in the Company's near-term plans. Included in the workforce reduction were three senior executives. All affected employees were eligible for certain severance payments and continuation of benefits. The Company expects to realize annual expense savings of approximately $8.1 million from the reduction in work force and related operating expenses. Additionally, certain commercial programs were discontinued and related costs will no longer be incurred. Such commercial program expenses totaled approximately $5.0 million for the fourth quarter of 2005 and first quarter of 2006.

The Company incurred a restructuring charge of $4.8 million in the second quarter of 2006 associated with staff reductions and the close-out of certain commercial programs, which was accounted for in accordance with Statement of Financial Accounting Standards No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* and is identified separately on the Statement of Operations as Restructuring Charge. This charge included $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain commercial programs.

As of September 30, 2006, payments totaling $3.5 million had been made related to these items and $1.3 million were unpaid. Of the $1.3 million that was unpaid as of September 30, 2006, $1.0 million was included in accounts payable and accrued expenses and $0.3 million was classified as a long-term liability. A reconciliation of these amounts is set forth in the table below:

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
Restructuring Charge - Q2 2006	$ 2,497	$ 2,308	$ 4,805
Payments / Adjustments	(2,227)	(1,028)	(3,255)
Liability as of June 30, 2006	270	1,280	1,550
Payments / Adjustments - Q3 2006	(80)	(129)	(209)
Liability as of September 30, 2006	$ 190	$ 1,151	$ 1,341

Note 8 – Treasury Stock

Occasionally, certain members of the Company's management and certain consultants, pursuant to terms set forth in the Company's Amended and Restated 1998 Stock Incentive Plan, tender shares of the Company's common stock held by such persons in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. There were no such shares tendered during the nine months ended September 30, 2006.

As a result of the reduction in staff in the second quarter of 2006, for the nine months ended September 30, 2006, 37,382 shares of unvested restricted stock awards were cancelled and recorded as treasury stock.

Note 9 – Litigation

In connection with the shareholder class actions filed in the United States District Court for the Eastern District of Pennsylvania against the Company in May 2006 and consolidated in June 2006 under the caption "In re: Discovery Laboratories Securities Litigation", a Consolidated Amended Complaint was filed by the Mizla Group, the lead plaintiffs, on August 9, 2006, individually and on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between March 15, 2004 and June 6, 2006. The complaint names as defendants the Company, the Company's Chief Executive Officer, Robert J. Capetola and the Company's former Chief Operating Officer, Christopher J. Schaber. On September 14, 2006, the Company's counsel filed a Motion to Dismiss the Consolidated Amended Complaint and on November 1, 2006, the court dismissed the Consolidated Amended Complaint, without prejudice, and granted plaintiffs leave to file an amended Consolidated Amended Complaint by November 30, 2006. The Company has no information as to whether the plaintiffs plan to file an amended complaint with the court.

Two shareholder derivative complaints filed in May and June 2006, respectively, in the United States District Court for the Eastern District of Pennsylvania against the Company's Chief Executive Officer, Robert J. Capetola, and the Company's directors remain subject to a stipulation agreement between the parties providing that the Company is not required to respond to these consolidated complaints until 60 days following defendants' answer or a dispositive ruling on a motion to dismiss filed in response to the consolidated amended complaint in the class actions, described above.

If any of these actions proceed, the Company intends to vigorously defend them. The potential impact of such actions, all of which generally seek unquantified damages, attorneys' fees and expenses is uncertain. Additional actions based upon similar allegations, or otherwise, may be filed in the future. There can be no assurance that an adverse result in any such proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

The Company has from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination of its commercial programs (discussed in Note 7, above). Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, the Company believes they are unlikely to have a material adverse effect on its financial condition or results of operations. However, there can be no assurance that the Company will be successful in any proceeding to which it may be a party.

Note 10 – Subsequent Events

Restructuring of Quintiles Loan

On October 25, 2006, the Company and PharmaBio agreed to restructure the existing $8.5 million credit facility (PharmaBio loan) that was scheduled to mature on December 31, 2006. Under the restructuring, the maturity date of the loan has been extended by 40 months, from December 31, 2006 to April 30, 2010. Beginning October 1, 2006, interest on the loan will accrue at the prime lending rate of Wachovia Bank, N.A., subject to change when and as such rate changes, compounded annually. Prior to October 1, 2006, interest accrued at a rate equal to the greater of 8% or the prime rate plus 2% and was payable quarterly. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, will now be payable on the maturity date of the loan. The Company may repay the loan, in whole or in part, at any time without prepayment penalty or premium. For further discussion, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

In consideration of PharmaBio's agreement to restructure the loan, the Company and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase 1,500,000 shares of the Company's common stock at an exercise price equal to $3.5813 per share. The Warrant Agreement has a seven-year term and is exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the PharmaBio loan, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. In connection with the issuance of the warrant, the Company expects to recognize deferred financing costs as an intangible asset of approximately $1.9 million, to be amortized to interest expense ratably over the extended term of the loan.

Amendment to Capital Lease Financing Arrangement with GECC

In connection with the restructuring of the PharmaBio loan, on October 25, 2006, the Company and the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) entered into an Amendment No. 5 and Consent (GECC Amendment) to the Master Security Agreement dated December 20, 2002 between the Company and GECC. Under the GECC Amendment, GECC consented to the execution and delivery by the Company of the Security Agreement to PharmaBio and, in consideration of the consent and other amendments to the Master Security Agreement, the Company granted to GECC a security interest in substantially all of the Company's assets, with certain exceptions.

During the month of October 2006, the Company received financing under the Master Security Agreement in the amount of $378,945 in connection with the purchase of property and equipment. GECC's obligation to finance purchases of property and equipment under the Master Security Agreement expired October 31, 2006; however, GECC has agreed in the near term to discuss the Company's financing needs on a month to month basis. For further discussion, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

Financing pursuant to the CEFF

In October 2006, the Company completed a financing pursuant to the CEFF resulting in proceeds of $2.3 million from the issuance of 1,204,867 shares of the Company's common stock at an average price per share, after the applicable discount, of $1.91.

The Company is currently completing a financing pursuant to the CEFF and expects to realize proceeds of $3.0 million from the issuance of approximately 1.4 million shares of the Company's common stock at an average price per share, after the applicable discount, of approximately $2.20.

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

"Management's Discussion and Analysis of Financial Condition and Results of Operations" should be read in connection with our accompanying Consolidated Financial Statements (including the notes thereto) appearing elsewhere herein.

OVERVIEW

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

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. Our lead product is Surfaxin® (lucinactant). We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and have received two Approvable Letters in connection with this NDA.

In addition, we recently announced preliminary results from a Phase 2 clinical trial investigating the use of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. We are also developing Aerosurf™, a proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), for the treatment of infants at risk for respiratory failure. We are planning to initiate Phase 2 clinical studies with Aerosurf, potentially obviating the need for endotracheal intubation and conventional mechanical ventilation.

As part of our ongoing efforts to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, in March 2006 we announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS). We believe our SRT will also potentially address Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), cystic fibrosis and other respiratory conditions.

Following receipt of our second Approvable Letter and the occurrence in April 2006 of our previously announced manufacturing issues, we revised our expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. In June 2006, we also determined to voluntarily withdraw the Marketing Authorization Application (MAA) that we had filed with the European Medicines Agency (EMEA) for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. On September 28, 2006, we filed a briefing package with the FDA and requested a meeting. The purpose of this meeting is to clarify the issues identified by the FDA in the second Approvable Letter and reach agreement with the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. The FDA has notified us that a meeting has been scheduled for December 21, 2006. For further discussion, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations."

To respond to the anticipated financial impact of our revised timing for potential FDA approval and commercial launch in the U.S. of Surfaxin for the prevention of RDS in premature infants, we have lowered our cost structure and re-aligned our operations to address our business priorities. In May 2006, we announced a reorganized management and a workforce reduction primarily affecting our commercial infrastructure, the development of which is no longer in our near-term plans. We also concluded our Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants and announced preliminary results in October 2006. For a discussion of these events, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Q2 2006 Restructuring Charge" and "Plan of Operations - Research and Development."

In addition, our revised expectations concerning the timing of potential FDA approval have had a significant impact on our business strategy. We are now implementing a business strategy which includes:

- taking actions intended to gain regulatory approvals for Surfaxin for the prevention of RDS in premature infants in the United States, preparing to attend the meeting with the FDA in December 2006, addressing questions raised in the second Approvable Letter, which focused on the CMC portion of our NDA, and preparing our response to the second Approvable Letter and completing the comprehensive investigation, analysis and remediation of our recent manufacturing issues;

- investing in the continued development of SRT pipeline programs, including Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);

- continued investment in our quality systems and our manufacturing capabilities at our manufacturing operation in Totowa, New Jersey, which we acquired in December 2005 to produce surfactant drug products to meet anticipated clinical and commercial requirements (if approved) of Surfaxin as well as pre-clinical, clinical and future commercial needs (if approved) of our SRT product candidates. We are implementing a manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential new formulations, and expansion of our aerosol SRT products, beginning with Aerosurf. Our strategy also includes, where appropriate, contracting with third-party manufacturers and potentially building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug and drug device combination products; and

- raising additional working capital and potentially securing additional strategic partnerships for the development and commercialization of our proprietary SRT product candidates, including Surfaxin. We have engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our surfactant replacement therapy pipeline and maximize shareholder value. We are evaluating multiple strategic alternatives including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities, although no assurances can be given that this evaluation will lead to any specific action or transaction.

Since our inception, we have incurred significant losses and, as of September 30, 2006, we had an accumulated deficit of $240.5 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities and, during 2005 and the first half of 2006, also include significant general and administrative, primarily pre-commercialization activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and developing manufacturing capabilities. We expense research and development costs as they are incurred. General and administrative expenses consist primarily of Surfaxin pre-launch commercialization sales and marketing (which were discontinued following our corporate reorganization announced in May 2006), executive management, financial, business development, legal and general corporate activities and related expenses. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.”

Historically, we have funded our operations with working capital provided principally through public and private equity financings, debt arrangements and strategic collaborations. As of September 30, 2006, we had: (i) cash of $19.7 million; (ii) approximately 10.6 million shares potentially available for issuance under the CEFF with Kingsbridge for future financings (not to exceed $47.8 million), subject to the terms and conditions of the agreement; (iii) a capital equipment lease financing arrangement with General Electric Capital Corporation (GECC) which was available through October 31, 2006, of which an aggregate of $7.5 million was drawn during the life of the facility and, after giving effect to principal payments, $5.0 million of which was still payable (after taking into account an additional $378,945 drawn in October 2006); and (iv) a $8.5 million loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), an investment group of Quintiles Transnational Corp., which, after a recent restructuring, is due and payable, together with all accrued interest, on April 30, 2010. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.”

RESEARCH AND DEVELOPMENT

Research and development expenses for the three and nine months ended September 30, 2006 were $5.2 million and $18.7 million, respectively, and for the three and nine months ended September 30, 2005 were $5.7 million and $16.7 million, respectively. These costs are charged to operations as incurred and are tracked by category rather than by project. Research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations and other direct clinical trials activities.

These cost categories typically include the following expenses:

Research and Pre-Clinical Operations

Research and pre-clinical operations, primarily conducted at our operations located in California, reflects activities associated with research prior to the initiation of any potential human clinical trials as well as analytical chemistry activities to support the continued development of Surfaxin. Pre-clinical activities predominantly represent projects associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and engineering of aerosol delivery systems to potentially treat a range of respiratory disorders prevalent in the NICU and the hospital. Research and pre-clinical operations costs primarily reflect expenses incurred for personnel, consultants, facilities and research and development arrangements with collaborators (including a research funding and option agreement with The Scripps Research Institute which expired in February 2005).

Manufacturing Development

Manufacturing development primarily reflects costs incurred to develop current good manufacturing practices (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Manufacturing development activities include (1) costs associated with operating our manufacturing facility in Totowa, New Jersey (which we acquired from our then-contract manufacturer, Laureate Pharma, Inc. (Laureate) in December 2005) to support the production of clinical and anticipated commercial drug supply for the Company's SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; and (2) continued investment in the Company's quality assurance and analytical chemistry capabilities, including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding the operations to meet production needs for our SRT pipeline in accordance with cGMP. In addition, manufacturing activities include expenses associated with our ongoing comprehensive investigation, analysis of the April 2006 Surfaxin process validation stability failure and remediation of the Company's related manufacturing issues.

Unallocated Development -- Clinical and Regulatory Operations

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

Direct Expenses -- Clinical Trials

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

The following summarizes our research and development expenses by the foregoing categories for the three and nine months ended September 30, 2006 and 2005:

(in thousands)

Research and Development Expenses:	Three Months Ended September 30, 2006[1]	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2006[1]	Nine Months Ended September 30, 2005
Research and pre-clinical operations	$ 470	$ 448	$ 1,538	$ 1,803
Manufacturing development	2,341	2,950	7,732	6,997
Unallocated development - clinical and regulatory operations	1,753	1,874	6,291	5,356
Direct clinical trial expenses	640	404	3,167	2,504
Total Research and Development Expenses	$ 5,204	$ 5,676	$ 18,728	$ 16,660

(1) Included in research and development expenses for the three and nine months ended September 30, 2006 is a charge of $0.3 million and $1.2 million associated with stock-based employee compensation in accordance with the provisions of FAS No. 123(R).

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

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical or pre-clinical development. The status and anticipated completion date of each of our lead SRT programs are discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations,” below. Successful completion of development of our SRT is contingent on numerous risks, uncertainties and other factors, some of which are described in detail in the section entitled “Risk Factors.”

Development risk factors include, but are not limited to:

- Completion of pre-clinical and clinical trials of our product candidates with the scientific results that are sufficient to support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant active drug substances on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Obtaining strategic partnerships and collaboration agreements for the development of our SRT pipeline, including Surfaxin;
- Performance of our third-party collaborators and suppliers on whom we rely for supply of drug substances and related services necessary to manufacture our SRT drug product candidates, including Surfaxin;
- Timely resolution of the Chemistry, Manufacturing and Controls (CMC) and cGMP-related matters at our manufacturing operations in Totowa, New Jersey with respect to Surfaxin and our other SRTs presently under development, including those we have identified in connection with our recent process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- Successful manufacture of SRT drug product candidates, including Surfaxin, at our operations in New Jersey;
- Successful development and implementation of a manufacturing strategy for the Chrysalis aerosolization device and related materials to support clinical studies and commercialization of Aerosurf; and
- Obtaining additional manufacturing operations, for which we presently have limited resources.

Because these factors, many of which are outside our control, could have a potentially significant effect on our activities, the success, timing of completion, and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- Slow patient enrollment;

- Long treatment time required to demonstrate effectiveness;
- Lack of sufficient clinical supplies and material;
- Adverse medical events or side effects in treated patients;
- Lack of compatibility with complimentary technologies;
- Lack of effectiveness of the product candidate being tested; and
- Lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. If we do not obtain and maintain regulatory approval and generate revenues from the sale of our products, such a failure would have a material adverse effect on our value, financial condition and results of operations.

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as ALI, neonatal respiratory failure, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung.

Chrysalis has developed a proprietary aerosol generation technology that is being designed with the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications. The Chrysalis technology is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery. Aerosols are created by pumping the drug formulation through a small, heated capillary wherein the excipient system is substantially converted to the vapor state. Upon exiting the capillary, the vapor stream quickly cools and slows in velocity yielding a dense aerosol with a defined particle size. The defined particle size can be readily controlled and adjusted through device modifications and drug formulation changes.

The alliance focuses on therapies for hospitalized patients, including those in the NICU, pediatric intensive care unit (PICU) and the adult intensive care unit (ICU), and can be expanded into other hospital applications and ambulatory settings. We and Chrysalis are utilizing our respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products. We have exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Generally, Chrysalis will receive a tiered royalty on product sales: the base royalty generally applies to aggregate net sales of less than $500 million per contract year; the royalty generally increases on aggregate net sales in excess of $500 million per contract year, and generally increases further on aggregate net sales of alliance products in excess of $1 billion per contract year.

Our lead neonatal program utilizing the Chrysalis technology is Aerosurf, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. We are planning an adult program utilizing the Chrysalis technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI.

Laboratorios del Dr. Esteve, S.A.

In December 2004, we restructured our strategic alliance with Esteve for the development, marketing and sales of our products in Europe and Latin America. Under the revised alliance, we regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay us a transfer price on sales of Surfaxin and other SRT. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory. Esteve has agreed to make stipulated cash payments to us upon its achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceutici S.p.A. (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution of Surfaxin in Italy.

PLAN OF OPERATIONS

We have incurred substantial losses since inception and expect to continue to expend substantial amounts for continued product research, development, manufacturing, and general business activities. We anticipate that during the next 12 to 24 months:

Research and Development

We will focus our research, development and regulatory activities in an effort to develop a pipeline of potential SRT for respiratory diseases. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the applicable risks discussed in the "Risk Factors" section herein and those contained in our most recent Annual Report on Form 10-K.

Our major research and development projects include:

SRT for Neonatal Intensive Care Unit

In order to address the most prevalent respiratory disorders affecting infants in the NICU, we are conducting several NICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal community.

Surfaxin for the Prevention of RDS in Premature Infants
In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested certain information primarily focused on the CMC section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous reviews, the FDA did not have any clinical or statistical comments. Also in April, ongoing analysis of data from Surfaxin process validation batches that were manufactured as a requirement for our NDA indicated that certain stability parameters had not been achieved. As a result of this process validation stability failure, three new process validation batches will have to be manufactured and submitted to ongoing process validation stability testing.

On September 28, 2006, we submitted an information package and requested a meeting with the FDA. The information package covered certain key CMC matters contained in the second Approvable Letter and provided information concerning our comprehensive investigation into the April 2006 Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. The purpose of the meeting is to clarify the issues identified by the FDA in the second Approvable Letter and reach agreement with the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. The FDA has notified us that a meeting has been scheduled for December 21, 2006.

Although our comprehensive investigation into the process validation stability failure is ongoing, we have developed and analyzed substantial data and believe that we will be able to remediate the Surfaxin manufacturing issues to our satisfaction and, to meet FDA requirements for our NDA, expect to manufacture new process validation batches prior to year-end 2006. Once we have achieved satisfactory Surfaxin process validation stability testing over an acceptable period (currently contemplated to be six months) and have finalized our response to the second Approvable Letter, we will submit to the FDA our formal response to the second Approvable Letter. The FDA will then advise us if it will accept the submitted response to the second Approvable Letter as a "complete" response and the time frame in which it will complete its review of the NDA.

In September 2006, we announced that, although our comprehensive investigation is ongoing, we believe we have identified a most probable root cause of the process validation stability failures. Our investigation continues, however, and may identify other contributing factors or causes for the process validation stability failure. The investigation is being conducted in compliance with FDA cGMP requirements and covers, among other things, analysis of manufacturing processes; equipment and process validation; manufacturing components; drug substances manufacturers; review and assessment of out-of-specification and deviation reports; analytical methods and method validation; and change control documentation. As part of the investigation, in addition to a variety of audits, tests and experiments, we have manufactured three "investigation batches" of Surfaxin that have passed the critical release specification assays, with stability monitoring ongoing. These investigation batches are not designated as process validation batches but are expected to provide significant data that will support comprehensive investigation report and a corrective action and preventative action (CAPA) plan.

In October 2004, we filed an MAA with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. At the time of the Surfaxin process validation stability failure, we had responded to the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) and had met with the EMEA to discuss our response. Because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMEA, we determined in June 2006 to voluntarily withdraw the MAA for Surfaxin for the prevention and rescue treatment of RDS in premature infants. We plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe.

Surfaxin for BPD in Premature Infants

In October 2006, we announced preliminary results of our recently completed Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD. The BPD Phase 2 clinical trial was a double-blind, controlled trial designed to enroll up to 210 very low birth weight premature infants born at risk for developing BPD. Total enrollment in the trial was 136 premature infants who received either Surfaxin standard dose (175 mg/kg), Surfaxin low dose (90 mg/kg), or sham air as a control. The study's objective was to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD and was not powered to determine statistically significant differences in outcomes. Key preliminary findings observed in this Phase 2 BPD trial include: a positive acute pharmacological response to Surfaxin therapy evidenced by a reduction in supplemental oxygen and ventilatory support; a lower incidence of death or BPD in patients receiving the Surfaxin standard dose compared with control (57.8% vs. 65.9%, respectively); a higher survival rate through 36 weeks post-menstrual age (PMA) in patients receiving the Surfaxin standard dose compared with control (88.9% vs. 84.1%, respectively); a reduction in duration of mechanical ventilation (approximately four less days) and need for supplemental oxygen in patients receiving the Surfaxin standard dose compared with control; and Surfaxin therapy was generally safe and well tolerated with generally no differences between the Surfaxin treatment groups and the control group in common complications of prematurity. By chance, infants assigned to the Surfaxin low dose treatment group were significantly sicker, with more pre-existing medical risk factors, such that the data from this treatment group cannot be easily interpreted and no meaningful conclusions can be drawn. We believe that the foregoing results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD.

Comprehensive analysis of the data from this trial is ongoing. Following this analysis, in collaboration with our Steering Committee and Investigators, we expect to present the study results to the medical community and submit the data for publication in a peer review journal. Presently there are no approved therapies for this disease. The FDA previously granted us Orphan Drug Status and Fast Track designations for Surfaxin for the prevention and treatment of BPD.

Aerosurf, Aerosolized SRT

Aerosurf is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failure. In September 2005, we completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf, which was designed as an open label, multicenter study to evaluate the feasibility, safety and tolerability of Aerosurf delivered using a commercially-available aerosolization device via nCPAP for the prevention of RDS in premature infants administered within 30 minutes of birth over a three hour duration. The study showed that it is feasible to deliver Aerosurf via nCPAP and that the treatment was generally safe and well tolerated.

In December 2005, we entered into a strategic alliance with Chrysalis. The alliance unites two highly complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. Through this alliance, we gained exclusive rights to their aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for neonatal respiratory disorders. We are presently collaborating with Chrysalis on the development of a prototype aerosolization device to deliver Surfaxin to patients in the NICU and, if successful, plan to initiate a pilot Phase 2 clinical study of Aerosurf utilizing the Chrysalis aerosolization technology in the middle of 2007. This timeline may be affected by any delay in our joint development activities related to the aerosolization device or by our efforts to remediate our manufacturing issues, discussed above.

SRT for Critical Care and Hospital Indications

In March 2006, we completed and announced preliminary results of a Phase 2 clinical trial for the treatment of ARDS in adults using our precision-engineered surfactant delivered via bronchoscopic segmental lavage (Surfactant Lavage). The ARDS Phase 2 clinical trial was an open-label, controlled, multi-center, international study of Surfactant Lavage for the treatment of ARDS in adults that was designed to enroll up to 160 patients. Total enrollment in the trial was 124 patients.

The objective of the Surfactant Lavage was to restore functional surfactant levels in the patients' lungs, thereby improving oxygenation in order to remove critically ill patients from mechanical ventilation sooner. Following our analysis of this trial, we plan to submit the data for publication in a peer review journal. We plan to seek potential partners, with which we can apply the scientific and clinical observations generated from this trial to support the design of potential future trials to treat ARDS.

We are also evaluating the development of aerosol formulations of SRT to potentially address ALI, cystic fibrosis, and other respiratory conditions. In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI. Given our current priority to focus on developing the SRT pipeline for the NICU, we will be assessing the timing and further prioritization of these adult programs.

Manufacturing

Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. Surfaxin is aseptically manufactured at our facility as a sterile, liquid suspension. The manufacturing process to produce Surfaxin is complex, must be conducted in a sterile environment, and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients.

We will invest in and support our manufacturing strategy for the production of our precision-engineered SRT to meet anticipated clinical needs and, if approved, commercial needs in the United States, Europe and other markets:

Manufacturing - New Jersey Operations

In December 2005, we purchased the manufacturing operations of Laureate (our contract manufacturer at that time) that are critical to the production of Surfaxin and our SRT clinical programs. This facility is our only validated clinical facility in which we produce clinical grade material of our drug substance. We will use this pharmaceutical manufacturing and development facility for the production of Surfaxin and for the development and new formulations of Surfaxin and the development of aerosol formulations including Aerosurf. In connection with our acquisition of the facility, we entered into a transitional services arrangement under which Laureate agreed to provide us with certain limited manufacturing-related support services through December 2006. In July 2006, we terminated the arrangement and have transitioned the Laureate support activities to our facility.

In April 2006, ongoing analysis of data from Surfaxin process validation batches that were manufactured as a requirement for our NDA indicated that certain stability parameters had not been achieved. As a result of this process validation stability failure, we will have to manufacture new process validation batches and submit them to ongoing process validation stability testing. Although our comprehensive investigation is ongoing, we have developed and analyzed substantial data and believe that we will be able to remediate the Surfaxin manufacturing issues to our satisfaction and, to meet FDA requirements for our NDA, expect to manufacture new process validation batches prior to year-end 2006. Once we have achieved satisfactory Surfaxin process validation stability testing over an acceptable period (currently contemplated to be six months) and have finalized our response to the second Approvable Letter, we will submit to the FDA our formal response to the second Approvable Letter. The FDA will then advise us if it will accept the submitted response to the second Approvable Letter as a “complete” response and the time frame in which it will complete its review of the NDA. We will continue to invest in manufacturing and regulatory activities intended to gain FDA approval, including in support of our response to the second Approvable Letter and the continuing comprehensive investigation and remediation of our recent manufacturing issues.

Longer-Term Manufacturing Capabilities

We view the acquisition of our New Jersey manufacturing facility as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential new formulations, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our New Jersey manufacturing facility extends through December 2014. In addition to the customary terms and conditions, the lease contains an early termination option, beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and, in the earlier years, payment to us of significant early termination amounts, subject to certain conditions. Taking into account this early termination option for our Totowa, New Jersey, facility, our long-term strategy includes, where appropriate, contracting with third-party manufacturers and potentially building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products.

Aerosol Devices and Related Componentry

For our planned clinical trials, we intend on utilizing third-party contract manufacturers, suppliers and assemblers for the aerosolization devices and related componentry for our aerosol SRT product candidates.

See the applicable risks discussed in the “Risk Factors” section herein and those contained in our most recent Annual Report on Form 10-K.

General and Administrative

We intend to invest in general and administrative resources primarily to support our legal requirements, intellectual property portfolios (including building and enforcing our patent and trademark positions), our business development initiatives, financial systems and controls, management information technologies, and general management capabilities.

We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability. Through September 30, 2006, we had no 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 suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through September 30, 2006, we had not generated taxable income. On December 31, 2005, net operating losses available to offset future taxable income for Federal tax purposes were approximately $187.0 million. The future utilization of such loss carryforward may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we had a research and development tax credit carryforward of $3.8 million at December 31, 2005. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2009 through 2024.

RESULTS OF OPERATIONS

The net loss for the three and nine month periods ended September 30, 2006 was $8.0 million (or $0.13 per share) and $38.5 million (or $0.62 per share), respectively. The net loss for the three and nine month periods ended September 30, 2005 was $10.4 million (or $0.19 per share) and $29.5 million (or $0.56 per share), respectively.

On January 1, 2006, we adopted Financial Accounting Standards No. 123(R) (FAS 123(R)) using the modified prospective method, which resulted in the recognition of stock compensation expenses in the statement of operations during the three and nine months ended September 30, 2006 without adjusting the prior year three and nine month periods. The net loss for the three and nine months ended September 30, 2006 includes $0.9 million (or $0.02 per share) and $4.1 million (or $0.06 per share), respectively, of stock-based compensation expenses as a result of our adoption of FAS 123(R). Additionally, included in the GAAP net loss for the nine months ended September 30, 2006 is a restructuring charge of $4.8 million, or $0.08 per share, related to the staff reductions and the close-out of certain commercial programs in the second quarter of 2006. Excluding these charges, the net loss for the three and nine months ended September 30, 2006 was $7.1 million (or $0.11 per share) and $29.6 million (or $0.48 per share), respectively.

Revenues

Revenue for the three and nine months ended September 30, 2006 was $0. Revenue for the three and nine months ended September 30, 2005 was $20,000 and $105,000, respectively. The revenue in 2005 was associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in Southern Europe.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2006 were $5.2 million and $18.7 million, respectively, and for the three and nine months ended September 30, 2005 were $5.7 million and $16.7 million, respectively. Research and development cost consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations and other direct clinical trial activities. The change as compared to the same prior year periods primarily reflects:

(i) manufacturing development activities (included in research and development expenses) include (1) costs associated with operating our manufacturing facility in Totowa, New Jersey (which we acquired from our then-contract manufacturer, Laureate in December 2005) to support the production of clinical and anticipated commercial drug supply for the Company's SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; and (2) continued investment in the Company's quality assurance and analytical chemistry capabilities, including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding the operations to meet production needs for our SRT pipeline in accordance with cGMP. In addition, manufacturing activities include expenses associated with our ongoing comprehensive investigation, analysis of the April 2006 Surfaxin process validation stability failure and remediation of the Company's related manufacturing issues. Expenses related to manufacturing development activities for the three and nine months ended September 30, 2006 were $2.3 million and $7.7 million, respectively, as compared to $3.0 million and $7.0 million for the three and nine months ended September 30, 2005, respectively. The increase in expenses for the nine months ended September 30, 2006 is primarily associated with the ownership of our manufacturing operation in Totowa, New Jersey, which we purchased from Laureate Pharma, Inc. (our contract manufacturer at that time) in December 2005. Expenditures in 2005 for manufacturing activities included improvements and enhancements to Laureate's Totowa, New Jersey facility in response to the FDA inspectional observations on Form FDA 483. Additionally, there was a charge of $0.1 million and $0.3 million for the three and nine months ended September 30, 2006, respectively, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

(ii) research and development activities, excluding manufacturing development activities, were $2.9 million and $11.0 million for the three and nine months ended September 30, 2006, respectively, as compared to $2.7 million and $9.7 million for the three and nine months ended September 30, 2005, respectively. These costs are primarily associated with clinical trial implementation and management, clinical quality control and regulatory compliance activities, data management and biostatistics, the development of aerosolized and other related formulations of our precision-engineered lung surfactant and engineering of aerosol delivery systems, including, among other things: (A) regulatory activities associated with Surfaxin for the prevention of RDS in premature infants; (B) clinical activities for the Phase 2 trial for ARDS in adults and the Phase 2 trial for BPD in premature infants; and (C) development activities related to Aerosurf for neonatal respiratory disorders. Additionally, there were charges of $0.2 million and $1.2 million for the three and nine months ended September 30, 2006, respectively, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2006 were $2.7 million and $15.4 million, respectively, and for the three and nine months September 30, 2005, were $4.8 million and $13.2 million, respectively. General and administrative expenses in 2006 include, but are not limited to, the costs of executive management, cost to defend the recently dismissed class action lawsuit, evaluating various strategic business alternatives, financial and legal management and other administrative costs.

The decrease in general and administrative expenses as compared to the same prior year periods primarily reflects, the discontinuance of commercial activities in the second quarter of 2006 to respond to the April 2006 Approvable Letter and Surfaxin process validation stability failure. For the three and nine months ended September 30, 2006, costs associated with these commercial activities were $0 million and $5.9 million, respectively, as compared to $2.7 million and $7.2 million for the three and nine months ended September 30, 2005, respectively. The costs associated with the discontinuance of commercial activities are a component of the Q2 2006 restructuring charge. Additionally, there is a charge of $0.6 million and $2.9 million for the three and nine months ended September 30, 2006, respectively, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

Q2 2006 Restructuring Charge

In April 2006, we reduced our staff levels and reorganized corporate management to lower our cost structure and re-align our operations with changed business priorities. These actions were taken in response to our revised expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants following the April 2006 Surfaxin process validation stability failure.

The reduction in workforce totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on our commercial infrastructure, the development of which is no longer in our near-term plans. Included in the workforce reduction were three senior executives. All affected employees were eligible for certain severance payments and continuation of benefits. We expect to realize annual expense savings of approximately $8.1 million from the reduction in work force and related operating expenses. Additionally, certain commercial programs were discontinued and related costs will no longer be incurred. Such commercial program expenses totaled approximately $5.0 million for the fourth quarter of 2005 and first quarter of 2006.

We incurred a restructuring charge of $4.8 million in the second quarter of 2006 associated with staff reductions and the close-out of certain commercial programs, which was accounted for in accordance with Statement of Financial Accounting Standards No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* and is identified separately on the Statement of Operations as Restructuring Charge. This charge included $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain commercial programs.

As of September 30, 2006, payments totaling $3.5 million had been made related to these items and $1.3 million were unpaid. Of the $1.3 million that was unpaid as of September 30, 2006, $1.0 million was included in accounts payable and accrued expenses and $0.3 million was classified as a long-term liability.

Other Income/(Expense)

Other income and (expense) for the three and nine months ended September 30, 2006 was ($71,000) and $474,000, respectively, compared to $67,000 and $189,000 for the three and nine months ended September 30, 2005.

Included in other income for the nine months ended September 30, 2006 was $280,000 of proceeds from the sale of our Commonwealth of Pennsylvania research and development tax credits.

Interest income for the three and nine months ended September 30, 2006 was $0.3 million and $1.2 million, respectively, compared to $0.3 million and $0.9 million for the three and nine months ended September 30, 2005. The increase is primarily due to a general increase in earned market interest rates.

Interest expense for the three and nine months ended September 30, 2006 was ($0.4) million and ($1.0) million, respectively, compared to ($0.3) million and ($0.7) million for the three and nine months ended September 30, 2005. The increase is primarily due to interest expense associated with our credit facility and capital lease financing arrangements. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

Cash is required to fund our working capital needs, to purchase capital assets, and to pay our debt service, including principal and interest payments. We do not currently have any source of operating revenue and will require significant amounts of cash to continue to fund our operations, our clinical trials and our research and development efforts until such time, if ever, that one of our products has received regulatory approval for marketing. Because we have not generated any revenue from the sale of any products, we have primarily relied on the capital markets and debt financings as our source of funding. We will continue to be opportunistic in accessing the capital markets to obtain financing on terms satisfactory to us. We plan to fund our future cash requirements through:

- the issuance of equity and debt financings;
- payments from potential strategic collaborators, including license fees and sponsored research funding;
- sales of Surfaxin, if approved;

- sales of our other product candidates, if approved;
- capital lease financings; and
- interest earned on invested capital.

Receipt of a second Approvable Letter and the occurrence of manufacturing issues in April 2006 (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations") caused us to modify our expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin. The related decline in market value of our common stock has made it more difficult to obtain equity and debt financing on terms that would be beneficial to us in the long term. We have engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. We are evaluating multiple strategic alternatives including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities. No assurances can be given that this evaluation will lead to any specific action or transaction.

After taking into account the recently implemented cost containment measures and the restructuring of the PharmaBio loan and before taking into account any strategic alternatives, potential financings or amounts that may be potentially available through the CEFF, we believe that our current working capital is sufficient to meet planned activities into mid-2007. Use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of common stock that we may issue under the CEFF (approximately 10.6 million shares were available for issuance under the CEFF as of September 30, 2006). In addition, during the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount we had initially specified. We anticipate using the CEFF, when available, to support working capital needs in 2006 and 2007.

We will need additional financing from investors or collaborators to complete research and development, manufacturing, and commercialization of our current product candidates under development, and satisfy debt obligations. Working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, the timing and cost of obtaining regulatory approvals, remediation of manufacturing issues, costs implementing programs related to our response to the second Approvable Letter, including tightening of active ingredient and drug product specifications and related quality controls, levels of resources that we devote to the further development of manufacturing and product development capabilities, the cost of drug substances, devices and materials used in our manufacturing activities, technological advances, status of competitors, ability to establish collaborative arrangements and strategic partnerships with other organizations, the ability to defend and enforce intellectual property rights, litigation and regulatory activities, and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2006, we had cash, cash equivalents, restricted cash and marketable securities of $19.7 million, as compared to $50.9 million as of December 31, 2005, a decrease of $31.2 million. The decrease primarily consists of cash used in operating and investing activities of $34.1 million, offset by $2.2 million of proceeds from a financing pursuant to the CEFF that resulted in the issuance of 1,078,519 shares of our common stock and $0.7 million of proceeds from the exercise of stock options and warrants.

In October 2006, we completed a financing pursuant to the CEFF resulting in proceeds of $2.3 million from the issuance of 1,204,867 shares of our common stock at an average price per share, after the applicable discount, of $1.91.

We are currently completing a financing pursuant to the CEFF and expect to realize proceeds of $3.0 million from the issuance of approximately 1.4 million shares of our common stock at an average price per share, after the applicable discount, of approximately $2.20.

Committed Equity Financing Facility

In April 2006, we entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of our common stock. Our previous Committed Equity Financing Facility, entered into with Kingsbridge in July 2004 (2004 CEFF) and which had capital of up to $47.6 million available, automatically terminated on May 12, 2006, the date on which the SEC declared effective the registration statement filed in connection with the new CEFF. We currently have approximately 8.0 million shares available for issuance under the CEFF for future financings (not to exceed $42.5 million in gross proceeds).

This CEFF allows us to raise capital, subject to certain conditions that we must satisfy, at the time and in amounts deemed suitable to us, during a three-year period that began on May 12, 2006. We are not obligated to utilize the entire $50 million available under this CEFF.

The purchase price of the shares sold to Kingsbridge will be at a discount ranging from 6 to 10 percent of the volume weighted average of the price of our common stock (VWAP) for each of the eight trading days following our election to sell shares, or "draw down" under the CEFF. The discount on each of these eight trading days will be determined as follows:

VWAP*	**% of VWAP (Applicable Discount)**	
Greater than $10.50 per share	94%	(6)%
Less than or equal to $10.50 but greater than $7.00 per share	92%	(8)%
Less than or equal to $7.00 but greater than or equal to $2.00 per share	90%	(10)%

* As such term is set forth in the Common Stock Purchase Agreement.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount we had initially specified.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of our outstanding shares of our common stock at the time of the draw down or $10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. In addition, Kingsbridge may terminate the CEFF under certain circumstances, including if a material adverse effect relating to our business continues for ten trading days after notice of the material adverse effect.
In connection with the new CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant must be exercised for cash, except in limited circumstances.

In connection with the new CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our common stock at an exercise price of $5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant must be exercised for cash, except in limited circumstances.

In May 2006, we entered into a financing pursuant to the CEFF resulting in proceeds of $2.2 million from the issuance of 1,078,519 shares of our common stock at an average price per share, after the applicable discount, of $2.03.

In October 2006, we completed a financing pursuant to the CEFF resulting in proceeds of $2.3 million from the issuance of 1,204,867 shares of our common stock at an average price per share, after the applicable discount, of $1.91.

We are currently completing a financing pursuant to the CEFF and expect to realize proceeds of $3.0 million from the issuance of approximately 1.4 million shares of our common stock at an average price per share, after the applicable discount, of approximately $2.20.

In 2004 and in connection with the 2004 CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to $12.0744 per share. The warrant, which expires in January 2010, must be exercised for cash, except in limited circumstances, for total proceeds equal to approximately $4.5 million, if exercised. As of September 30, 2006, the Class B Investor Warrant had not been exercised in whole or in part.

Potential Financings under the October 2005 Universal Shelf Registration Statement

In October 2005, we filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering, from time to time, of up to $100.0 million of our debt or equity securities. In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to us of $20.0 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $80.0 million of equity or debt securities. There can be no assurance, however, that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our research and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

Debt Facilities

Credit Facility with PharmaBio, an Investment Group of Quintiles Transnational Corp.

We entered into a collaboration arrangement with Quintiles Transnational Corp. (Quintiles), in 2001, to provide certain commercialization services in the United States for Surfaxin for the prevention of RDS in premature infants and Meconium Aspiration Syndrome in full-term infants. In connection with the commercialization agreement, PharmaBio, Quintiles strategic investment group, extended to us a secured, revolving credit facility of $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. The facility was renegotiated in November 2004. At September 30, 2006, $8.5 million was outstanding under the credit facility. On October 25, 2006, we and PharmaBio agreed to restructure the existing $8.5 million credit facility (PharmaBio loan) that was scheduled to mature on December 31, 2006. Under the restructuring, the maturity date of the PharmaBio loan has been extended by 40 months, from December 31, 2006 to April 30, 2010. Prior to October 1, 2006, interest accrued at a rate equal to the greater of 8% or the prime rate plus 2% and was payable quarterly. Beginning on October 1, 2006, interest on the loan will accrue at the prime lending rate of Wachovia Bank, N.A., subject to change when and as such rate changes, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, will now be payable on April 30, 2010, the maturity date of the PharmaBio loan. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium.

In connection with the restructuring, on October 25, 2006, we and PharmaBio entered into a Second Amended and Restated Loan Agreement (Loan Agreement) and a Second Amended and Restated Security Agreement (Security Agreement). Pursuant to the Loan Agreement, we have issued to PharmaBio a Second Amended and Restated Promissory Note (Note), which replaces and supersedes the note dated as of December 10, 2001 as amended and restated as of November 3, 2004. Our obligation to PharmaBio under the Note, the Loan Agreement and the Security Agreement are secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the Security Agreement (the PharmaBio Collateral).

On October 25, 2006, in consideration of PharmaBio's agreement to restructure the loan, we and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase 1,500,000 shares of our common stock, par value $0.001 per share, at an exercise price equal to $3.5813 per share, which represents a 30% premium over the VWAP (as reported by Bloomberg, L.P.) of our common stock for the ten trading days immediately preceding the date of the Warrant Agreement. The warrants granted under the Warrant Agreement have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we have agreed to file a registration statement with the SEC within 45 days of October 25, 2006 with respect to the resale of the shares issuable upon exercise of the warrants. The warrants were issued to PharmaBio in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Capital Lease and Note Payable Financing Arrangements with General Electric Capital Corporation

Our capital lease financing arrangements have been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) pursuant to a Master Security Agreement dated December 20, 2002 (Master Security Agreement). The Master Security Agreement, which previously had been extended, expired October 31, 2006; however, GECC has agreed in the near term to discuss our capital financing needs on a month to month basis. We are also considering alternative capital financing arrangements. There is no assurance, however, that we will receive additional financing from GECC or secure an alternate source to finance our capital lease needs in the future.

Under the Master Security Agreement, we purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through capital leases. The capital leases are secured by the related assets. Laboratory and manufacturing equipment is financed over 48 months and all other equipment is financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. As of September 30, 2006, $4.8 million is outstanding ($1.9 million classified as current liabilities and $2.9 million as long-term liabilities) and $1.5 million remained available for future use, subject to certain conditions. In October 2006, we drew an additional $378,945 in connection with the purchase of property and equipment.

In connection with the restructuring of the PharmaBio loan, on October 25, 2006, we and GECC entered into an Amendment No. 5 and Consent (GECC Amendment) to the Master Security Agreement, pursuant to which GECC consented to our execution and delivery of the Security Agreement to PharmaBio and, in consideration of the consent and other amendments to the Master Security Agreement, we granted to GECC, as additional collateral under the Master Security Agreement, a security interest in the PharmaBio Collateral. We, GECC and PharmaBio also entered into an Intercreditor Agreement, pursuant to which GECC agreed to subordinate its security interest in the PharmaBio Collateral to PharmaBio's security interest in the PharmaBio Collateral. GECC retains a first priority security interest in the property and equipment financed under the Master Security Agreement, which are not a part of the PharmaBio Collateral. Under the GECC Amendment, GECC will release its security interest in the PharmaBio Collateral upon (a) receipt by us of FDA approval for Surfaxin for the prevention of RDS in premature infants or (b) the occurrence of certain milestones to be agreed. If the parties are unable to agree on milestones or if we elect to prepay all of our indebtedness to GECC at a time when GECC holds a security interest in the PharmaBio Collateral, we may do so without prepayment penalty.

Lease Agreements

We maintain facility leases for our operations in Pennsylvania, New Jersey and California.

We maintain our headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, sales and marketing, and administration. The lease expires in February 2010 with total aggregate payments of $4.6 million.

We lease a 21,000 square foot pharmaceutical manufacturing and development facility in Totowa, New Jersey that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements. The lease expires in December 2014 with total aggregate payments of $1.4 million ($150,000 per year). The lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to us, subject to certain conditions.

In August 2006, we extended the lease on our office and laboratory space in Doylestown, Pennsylvania. We reduced our leased space from approximately 11,000 square feet to approximately 5,600 square feet. We maintain the Doylestown facility for the continuation of analytical laboratory activities under a lease that expires in May 2007, and is subject to extensions on a monthly basis.

We lease office and laboratory space in Mountain View, California. The facility is 16,800 square feet and houses our aerosol and formulation development operations. The lease expires in June 2008 with total aggregate payments of $804,000.

Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our manufacturing and research and product development activities and to repay our indebtedness. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our CEFF with Kingsbridge, we currently do not have any contractual arrangements under which we may obtain additional financing.

On June 20, 2006, we announced that we had engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist us in identifying and evaluating strategic alternatives intended to generate additional funds and enhance the future growth potential of our surfactant replacement therapy pipeline and maximize shareholder value. We are considering multiple strategic alternatives, including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities. No assurances can be given that this evaluation will lead to any specific action or transaction.

If a transaction involving the issuance of additional equity and debt securities is concluded, such a transaction may result in additional dilution to our shareholders. We cannot be certain that additional funding will be available when needed or on terms acceptable to us, if at all. If we fail to receive additional funding or enter into business alliances or other similar opportunities, we may have to reduce significantly the scope of or discontinue our planned research, development and manufacturing activities, which could significantly harm our financial condition and operating results.

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

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that as of the end of the period covered by this report, the disclosure controls and procedures were effective in their design to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Changes in internal controls

There were no changes in internal controls over financial reporting or other factors that could materially 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

In connection with the shareholder class actions filed in the United States District Court for the Eastern District of Pennsylvania against the Company in May 2006 and consolidated in June 2006 under the caption "In re: Discovery Laboratories Securities Litigation", a Consolidated Amended Complaint was filed by the Mizla Group, the lead plaintiffs, on August 9, 2006, individually and on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between March 15, 2004 and June 6, 2006. The complaint names as defendants the Company, the Company's Chief Executive Officer, Robert J. Capetola and the Company's former Chief Operating Officer, Christopher J. Schaber. On September 14, 2006, the Company's counsel filed a Motion to Dismiss the Consolidated Amended Complaint and on November 1, 2006, the court dismissed the Consolidated Amended Complaint, without prejudice, and granted plaintiffs leave to file an amended Consolidated Amended Complaint by November 30, 2006. The Company has no information as to whether the plaintiffs plan to file an amended complaint with the court.

Two shareholder derivative complaints filed in May and June 2006, respectively, in the United States District Court for the Eastern District of Pennsylvania against the Company's Chief Executive Officer, Robert J. Capetola, and the Company's directors remain subject to a stipulation agreement between the parties providing that the Company is not required to respond to these consolidated complaints until 60 days following defendants' answer or a dispositive ruling on a motion to dismiss filed in response to the consolidated amended complaint in the class actions, described above.

If any of these actions proceed, the Company intends to vigorously defend them. The potential impact of such actions, all of which generally seek unquantified damages, attorneys' fees and expenses is uncertain. Additional actions based upon similar allegations, or otherwise, may be filed in the future. There can be no assurance that an adverse result in any such proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

The Company has from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination of its commercial programs (discussed in Note 7, above). Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, the Company believes they are unlikely to have a material adverse effect on its financial condition or results of operations. However, there can be no assurance that the Company will be successful in any proceeding to which it may be a party.

ITEM 1A. RISK FACTORS

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.

The risk factors set forth below have been revised based on recent events related to the Company and described elsewhere in this report. These risk factors should be read together with the factors discussed in Part I, Item 1A - Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2005.

The risks described in this report and in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Refocusing our business subjects us to risks and uncertainties.

Since we received our second Approvable Letter from the FDA, we have been reassessing the business environment, our position within the biotechnology industry and our relative strengths and weaknesses. As a result of this reassessment, we have implemented significant changes to our operations as part of our overall business strategy. For example, we have reduced the size of our workforce and made changes to senior management. Additional changes to our business will be considered as our management seeks to strengthen financial and operational performance. These changes may be disruptive to our established organizational culture and systems. In addition, consideration and planning of strategic changes diverts management attention and other resources from day to day operations.

We may fail to realize the benefits that we expect from our cost-savings initiatives.

We have undertaken and expect to continue to undertake cost-savings initiatives. However, we cannot assure you that we will realize on-going cost savings or any other benefits from these initiatives. Even if we realize the benefits of our cost savings initiatives, any cash savings that we achieve may be offset by other costs, such as costs related to ongoing development activities and pre-clinical and clinical studies. Staff reductions may reduce our workforce below the level needed to effectively manage our business and service our development programs. Our failure to realize the anticipated benefits of our cost-savings initiatives could have a material adverse effect on our business, results of operations and financial condition.

The regulatory approval process for our products is expensive and time-consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products.

To sell Surfaxin or any of our other products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators 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 foreign regulators that, in manufacturing the product, we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable testing data is generated by clinical trials of drug products, the FDA or EMEA may not accept or approve an NDA or MAA filed by a pharmaceutical or biotechnology company for such drug product. 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.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form FDA 483 to our then contract manufacturer, Laureate. The FDA cited inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with cGMPs. The FDA issued an Approvable Letter to us in February 2005 regarding our NDA. To address the Form FDA 483 inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In October 2005, the FDA accepted our responses to the Approvable Letter as a complete response thereby establishing April 2006 as its target to complete its review of our NDA. In April 2006, ongoing analysis of data from Surfaxin process validation batches that were manufactured as a requirement for our NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional process validation batches will have to be produced. In September 2006, we announced that, although our comprehensive investigation is ongoing, we believe we have identified a most probable root cause of the process validation stability failures. Our investigation continues, however, and may identify other contributing factors or causes for the process validation stability failure. There can be no assurance that we have identified or will identify the definitive root cause of the process validation stability failure. If we are unable to identify a definitive root cause, we may not be able to manufacture our drug product successfully within our expected timeline, if at all. The investigation is being conducted in compliance with FDA cGMP requirements, covers, among other things, manufacturing processes, test methods, and drug substance suppliers. As part of the investigation, in addition to a variety of audits, tests and experiments, we have manufactured three "investigation batches" of Surfaxin that have passed the critical release specification assays, with stability monitoring ongoing. These investigation batches are not designated as process validation batches but are expected to provide significant data that will support our comprehensive investigation report and a corrective action and preventative action (CAPA) plan. Also in April 2006, the FDA issued a second Approvable Letter to us, requesting certain information primarily focused on the CMC section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. On September 28, 2006, we filed a briefing package and requested a meeting with the FDA. The purpose of this meeting is to clarify the issues identified by the FDA in the second Approvable Letter and reach agreement with the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. The FDA has notified us that a meeting has been scheduled for December 21, 2006. Once we have achieved satisfactory Surfaxin process validation stability testing over an acceptable period (currently contemplated to be six months) and have finalized our response to the second Approvable Letter, we will submit to the FDA our formal response to the second Approvable Letter. At that time, the FDA will advise us if it will accept our response to the second Approvable Letter as a complete response and the time frame in which it will complete its review. Even if the FDA accepts our response as a complete response, the FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

We filed an MAA with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. At the time of the Surfaxin process validation stability failure, we had responded to the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) and had met with the EMEA to discuss our response. Because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMEA, we determined in June 2006 to voluntarily withdraw the MAA for Surfaxin for the prevention and rescue treatment of RDS in premature infants. We plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe.
See also Item 2: "Management's Discussion and Analysis of Financial Condition and Results of Operation - Overview and Plan of Operations."

Our pending NDA for Surfaxin for the prevention of RDS in premature infants may not be approved by the FDA in a timely manner or at all, which would adversely impact our ability to commercialize this product.

We submitted an NDA to the FDA for Surfaxin for the prevention of RDS in premature infants. In April 2006, we received a second Approvable Letter from the FDA. Specifically, the FDA requested certain information primarily focused on the CMC section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. . Thereafter, we learned that ongoing analysis of data from Surfaxin process validation batches that were manufactured as a requirement for our NDA indicated that certain stability parameters had not been achieved and, therefore, three new Surfaxin process validation batches will have to be produced. These events have caused us to revise our expectations concerning the timing of potential FDA approval of our NDA. We are conducting a comprehensive investigation with a view to identify a definitive root cause of the process validation stability failure and implement a corrective action and preventative action (CAPA) plan. When we are satisfied that we have remediated our manufacturing issues, we will manufacture new process validation batches and, after we have achieved satisfactory Surfaxin process validation stability testing over an acceptable period (currently contemplated to be six months) and have finalized our response to the second Approvable Letter, we will submit to the FDA our formal response to the second Approvable Letter. Nevertheless, the FDA may request additional information from us, including data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product.

The manufacture of our products is a highly exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Manufacturing or quality control problems have already and may again occur at our Totowa facility or at our materials suppliers. Such problems, including, for example, our recent product stability testing program issues, require potentially complex, time-consuming and costly investigations to determine the root causes of such problems and may also require detailed and time-consuming remediation efforts, which can further delay the regulatory approval process. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

In December 2005, we acquired Laureate's clinical manufacturing facility in Totowa, New Jersey. The facility has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies. With this acquisition, we now maintain a complete manufacturing facility and we will be manufacturing our products. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we expect to invest in additional manufacturing equipment. However, we may be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards for use in clinical studies or commercialization. If we do not successfully develop our manufacturing capabilities, it will adversely affect the sales of our products.

In connection with the development of Aerosurf, we expect to rely on third-party contract manufacturers to manufacture the Chrysalis drug device products and components to support our clinical studies and potential commercialization of Aerosurf. Certain of the drug device components must be manufactured in a sterile environment, subject to ongoing monitoring of conformance to product specifications of each device. The manufacturer must be registered with and qualified by the FDA and must conduct its manufacturing activities in compliance with cGMP requirements, or those of foreign regulators. We may be unable to identify a qualified manufacturer to meet our requirements or the manufacturer we identify may be unable to timely comply with FDA, or other foreign regulatory agency, requirements to manufacture the drug product devices or such manufacturer may not manufacture to our specifications for use in clinical studies or, if approved, commercialization. If we do not successfully identify and enter into a contractual agreement with drug device and components manufacturers, it will adversely affect the timeline of our plans for development, the development plan and, if approved, commercialization of Aerosurf.

If the parties we depend on for supplying our active drug substance and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for our active drug substances and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards for use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. The manufacturing process for the drug product devices used in Aerosurf includes the integration of a number of products, many of which are comprised of a large number of subcomponent parts, that we expect will be produced by one or more manufacturers. We and our suppliers may not be able to (i) produce our drug substances, drug product or drug product devices to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor 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 and suppliers, 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 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 working capital will be adequate to satisfy our capital needs into mid-2007, before taking into account any amounts that may be available through the CEFF. 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 new capital lease arrangements, if available. 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 other than the CEFF with Kingsbridge, the PharmaBio loan and our capital equipment lease financing arrangement with GECC, which expired on October 31, 2006. Our use of the CEFF is subject to certain conditions, discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility” above. In addition, Kingsbridge has the right under certain circumstances to terminate the CEFF, including upon the occurrence of a material adverse event.

Our equipment lease financing arrangement with GECC expired on October 31, 2006. We continue to engage in discussions with GECC, which has agreed in the near term to discuss our financing needs on a month to month basis, and are considering alternative arrangements with other financing entities, there is no assurance that our discussions with GECC will be successful or that any alternative arrangements will be successfully concluded. If we are successful in arranging for property and lease financing arrangements, there is no assurance that such arrangements will be on terms that are favorable to us or sufficient to meet our capital financing needs over the term of the arrangement. If we do not obtain additional capital financing, we may not be able to execute on our business plan, in particular our manufacturing strategy, and be forced to delay or scale back our activities.

On June 20, 2006, we announced that we have engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist us in identifying and evaluating strategic alternatives intended to generate additional funds and enhance the future growth potential of our surfactant replacement therapy pipeline and maximize shareholder value. We are considering multiple strategic alternatives, including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities. No assurances can be given that this evaluation will lead to any specific action or transaction or generate additional capital for us.

If we seek additional financing, such additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to receive additional funding or enter into business alliances or other similar opportunities, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See also "Risk Factors: Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders."

Furthermore, if the market price of our common stock declines as a result of the dilutive aspects of such potential financings, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq Global Market. See "Risk Factors: The market price of our stock may be adversely affected by market volatility."

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

The issuance of shares of our common stock under the CEFF and upon exercise of the warrants we issued to Kingsbridge will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

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

We may not be able to meet the conditions we are required to meet under the CEFF and we may not be able to access any portion of the approximately 8.0 million shares potentially available for issuance for future financings (not to exceed $42.5 million), subject to the terms and conditions of the CEFF.

In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.

We do not have experience in marketing or selling pharmaceutical products. As a result of our recent manufacturing problems, we discontinued our commercial activities, which are no longer in our near-term plans. To achieve commercial success for Surfaxin, or any other approved product, we will be dependent upon entering into arrangements with others to market and sell our products.

We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates. To obtain the expertise necessary to successfully market and sell Surfaxin, or any other product, will require the development of collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

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 our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

In order to lower our cost structure and re-align our operations with business priorities, in April 2006, we reduced our staff levels and reorganized our corporate structure. The workforce reduction totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on commercial infrastructure, the development of which is no longer in our near-term plans. Included in the workforce reduction were three senior executives. As a consequence of this reduction in force, our dependence on our remaining management team is increased. If we find it necessary or advisable to hire additional managers, a portion of the expected cost savings from our recent restructuring might not be realized.

To retain and provide incentives to certain of our key continuing executives, we entered into amended and new employment agreements with our executive management and other officers, which agreements provide for employment for a stated term, subject to automatic renewal, severance payments in the event of termination of employment, enhanced severance benefits in the event of a change of control and equity incentives in the form of stock and option grants**.** Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. 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. 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.

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

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of September 30, 2006 we had 62,374,235 shares of common stock issued and outstanding.

We have a universal shelf registration statement on Form S-3 (File No. 333-128929), filed with the SEC on October 11, 2005, for the proposed offering from time to time of up to $100 million of our debt or equity securities, of which $80 million is remaining. We have no immediate plans to sell any securities under this registration statement. However, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

Additionally, there are 375,000 shares of our common stock that are currently reserved for issuance with respect to the Class B Investor Warrant and approximately 8.0 million shares of our common stock that are currently reserved for issuance under the CEFF, including 490,000 shares reserved for issuance with respect to the Class C Investor Warrant. See "Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

As of September 30, 2006, up to 12,407,431, shares of our common stock were issuable upon exercise of outstanding options and warrants. Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

The failure to prevail in litigation or the costs of litigation, including securities class action and patent claims, could harm our financial performance and business operations.

We are potentially susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws, as well as derivative actions. In particular, in early May 2006, four shareholder class actions and two derivative actions were filed in the United States District Court for the Eastern District of Pennsylvania against the Company and its Chief Executive Officer, Robert J. Capetola, Ph.D. Certain of the complaints also named other officers of the Company and certain of its directors. The class actions were consolidated under a Consolidated Amended Complaint, filed on August 9, 2006, and on November 1, 2006, the court dismissed the Consolidated Amended Complaint without prejudice and granted plaintiffs leave to file an amended Consolidated Amended Complaint by November 30, 2006. We have no information as to whether the plaintiffs plan to file an amended complaint with the court. Nevertheless, even if plaintiffs do not file a new complaint, **a**dditional actions may be filed against the Company arising out of the same or different events. Although we will aggressively defend any such actions, an adverse result in one or more of them could have a potentially material adverse effect on the Company's business, results of operations and financial condition.

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

During the three months ended September 30, 2006, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 25,472 shares of our common stock at various exercise prices ranging from $.0026 to $1.50 per share for an aggregate consideration equal to $12,045. 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.

We have a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, we allowed for periodic discretionary matches of newly issued shares of our common stock with the amount of any such match determined as a percentage of each participant's cash contribution. The total fair market value of our match of our common stock to the 401(k) for the three months ended September 30, 2006 was $80,394, resulting in the issuance of 44,270 shares.

There were no stock repurchases in the three and nine months ended September 30, 2006, however, during the nine months ended September 30, 2006, 37,382 shares of unvested restricted stock awards were cancelled and recorded as treasury stock.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 9, 2006

By: /s/ Robert J. Capetola

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

Date: November 9, 2006

By: /s/ John G. Cooper

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

INDEX TO EXHIBITS

The following exhibits are included with this Quarterly Report. All management contracts or compensatory plans or arrangements, if any, are marked with an asterisk.

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Certificate of Amendment to the Certificate of Incorporation of Discovery, dated as of May 28, 2004.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 9, 2004.
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of Discovery, dated as of July 8, 2005.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 8, 2005.
3.4	Amended and Restated By-Laws of Discovery.	Incorporated by reference to Exhibit 3.2 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the SEC on March 15, 2004.
3.5	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
4.1	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Form of Class E Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on March 29, 2000.
4.3	Form of Unit Purchase Option issued to Paramount Capital, Inc.	Incorporated by reference to Exhibit 4.4 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999, as filed with the SEC on March 30, 2000.
4.4	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.5	Class B Investor Warrant, dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.

Exhibit No.	Description	Method of Filing
4.6	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.7	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.8	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
4.9	Registration Rights Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.10	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. ("PharmaBio")	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.11	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.1	Amendment No.5 and Consent, dated as of October 25, 2006, to the Master Security Agreement between General Electric Capital Corporation and Discovery	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.2	Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.3	Second Amended and Restated Security Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

CERTIFICATIONS

I, Robert J. Capetola, certify that:

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

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2006

/s/ Robert J. Capetola

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

CERTIFICATIONS

I, John G. Cooper, certify that:

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

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2006

/s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2006 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2006

/s/ Robert J. Capetola

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

/s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer

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 SEC or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.