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

# FORM 10-Q

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

For the quarterly period ended June 30, 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 August 2, 2006, 62,320,630 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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**PART I - FINANCIAL 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 clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products; the research and development of particular compounds and technologies; 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);
- 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 that the FDA or other regulatory authorities may delay consideration of any applications that we file;
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that any such 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 relating to the ability of our third party materials suppliers and development partners to provide us with adequate supplies of drug substance and drug products for 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 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;
- 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.

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)*

| | June 30, 2006 (Unaudited) | December 31, 2005 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 26,627 | $ 47,010 |
| Restricted cash | 662 | 647 |
| Available-for-sale marketable securities | - | 3,251 |
| Prepaid expenses and other current assets | 348 | 560 |
| Total Current Assets | 27,637 | 51,468 |
| Property and equipment, net of accumulated depreciation | 4,583 | 4,322 |
| Other assets | 217 | 218 |
| Total Assets | $ 32,437 | $ 56,008 |
| **LIABILITIES & STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | $ 7,203 | $ 7,540 |
| Credit facility, current portion | 8,500 | 8,500 |
| Capitalized leases and note payable, current portion | 1,883 | 1,568 |
| Total Current Liabilities | 17,586 | 17,608 |
| Capitalized leases and note payable, non-current portion | 3,282 | 3,323 |
| Other liabilities | 679 | 239 |
| Total Liabilities | 21,547 | 21,170 |
| Stockholders' Equity: | | |
| Common stock, $0.001 par value; 180,000 shares authorized; 62,656 and 61,335 shares issued, and 62,321 and 61,022 shares outstanding at June 30, 2006 and December 31, 2005, respectively. | 63 | 61 |
| Additional paid-in capital | 246,514 | 240,028 |
| Unearned portion of compensatory stock options | (115) | (230) |
| Accumulated deficit | (232,455) | (201,965) |
| Treasury stock (at cost); 335 and 313 shares at June 30, 2006 and December 31, 2005, respectively. | (3,117) | (3,054) |
| Accumulated other comprehensive loss | -- | (2) |
| Total Stockholders' Equity | 10,890 | 34,838 |
| Total Liabilities & Stockholders' Equity | $ 32,437 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2006** | **2005** | **2006** | **2005** |
| Revenues: | | | | |
| Contracts and Grants | $ - | $ 24 | $ - | $ 85 |
| Expenses: | | | | |
| Research & Development | 5,911 | 5,864 | 13,524 | 10,984 |
| General & Administrative | 4,024 | 4,095 | 12,706 | 8,365 |
| Restructuring Charge | 4,805 | -- | 4,805 | -- |
| Total Expenses | 14,740 | 9,959 | 31,035 | 19,349 |
| Operating Loss | (14,740) | (9,935) | (31,035) | (19,264) |
| Other income / (expense): | | | | |
| Interest and other income | 377 | 342 | 1,177 | 556 |
| Interest and amortization expense | (332) | (233) | (632) | (434) |
| Other income / (expense), net | 45 | 109 | 545 | 122 |
| Net Loss | $ (14,695) | $ (9,826) | $ (30,490) | $ (19,142) |
| Net loss per common share - Basic and diluted | $ (0.24) | $ (0.18) | $ (0.50) | $ (0.37) |
| Weighted average number of common shares outstanding - basic and diluted | 61,652 | 53,587 | 61,411 | 52,029 |

*See notes to consolidated financial statements*

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2006** | **2005** |
| Cash flows from operating activities: | | |
| Net loss | $ (30,490) | $ (19,142) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 448 | 383 |
| Stock-based compensation expense / 401(k) match | 3,757 | 260 |
| Changes in: | | |
| Prepaid expenses and other current assets | 212 | (96) |
| Accounts payable and accrued expenses | (337) | (1,203) |
| Other assets | 1 | 12 |
| Other liabilities | 440 | (85) |
| Net cash used in operating activities | (25,969) | (19,871) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (709) | (396) |
| Restricted cash | (15) | -- |
| Purchases of marketable securities | (4,631) | (30,108) |
| Proceeds from sales or maturity of marketable securities | 7,884 | 7,872 |
| Net cash provided by / (used in) investing activities | 2,529 | (22,632) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of securities, net of expenses | 2,846 | 27,997 |
| Proceeds from credit facility | - | 2,571 |
| Equipment financed through capital lease obligation | 1,036 | 433 |
| Principal payments under capital lease obligation | (762) | (427) |
| Purchase of treasury stock | (63) | - |
| Net cash provided by financing activities | 3,057 | 30,574 |
| Net decrease in cash and cash equivalents | (20,383) | (11,929) |
| Cash and cash equivalents - beginning of period | 47,010 | 29,264 |
| Cash and cash equivalents - end of period | $ 26,627 | $ 17,335 |
| Supplementary disclosure of cash flows information: | | |
| Interest paid | $ 619 | $ 377 |
| Non-cash transactions: | | |
| Unrealized gain/(loss) on marketable securities | 2 | (15) |

*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, where 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 concluded patient enrollment 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 administered in aerosolized form, for the prevention and treatment of infants with respiratory distress. The Company is preparing to initiate Phase 2 clinical studies with Aerosurf administered through nasal continuous positive airway pressure (nCPAP), potentially obviating the need for endotracheal intubation and conventional mechanical ventilation.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, the Company is also developing its SRT to 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 RDS in premature infants in the United States, including preparing to respond to the second Approvable Letter and 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, primarily utilizing the aerosol generating technology rights licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in manufacturing capabilities at the manufacturing operations in New Jersey acquired by the Company in December 2005 to produce surfactant drug products to meet anticipated clinical and commercial needs (if approved) and, potentially, investing in additional facilities to be built or acquired by the Company in the future; and (iv) potentially entering into 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 six month period ended June 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 current products 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 presentations.

**Note 2 - Net Loss Per Share**

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

**Note 3 - 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 six months ended June 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 six months ended June 30, 2006 was $1.6 million (or $0.03 per share) and $3.2 million (or $0.05 per share), respectively, higher than if it had continued to account for share-based compensation under Opinion 25. For the three and six months ended June 30, 2006, $0.5 million and $0.9 million was classified as research and development and $1.1 million and $2.3 million 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 six months ended June 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 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 June 30, 2005 | Six Months Ended June 30, 2005 |
|---|---|---|
| Net loss, as reported | $ (9,826) | $ (19,142) |
| Net loss per share, as reported | $ (0.18) | $ (0.37) |
| Add: Stock-based employee compensation expense included in reported net loss | 4,014 | 4,633 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | - | - |
| Pro forma net loss | $ (13,840) | $ (23,775) |
| Pro forma net loss per share | $ (0.26) | $ (0.46) |

Stock Incentive Plan

The Company's 1998 Stock Incentive Plan (the Plan), which is shareholder-approved, permits the grant of share options and shares to its eligible employees, officers, consultants, independent advisors and non-employee directors for up to 11,232,000 shares of our common stock, of which 9,798,000 shares were outstanding and 1,434,000 were available at June 30, 2006. 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.

| | June 30, 2006 | June 30, 2005 |
|---|---|---|
| Expected volatility | 101% | 78% |
| Expected term (in years) | 5 years | 3.5 years |
| Risk-free rate | 5.0% | 3.9% |
| Expected dividends | 0% | 0% |

A summary of option activity under the Plan as of June 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 |

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 six months ended June 30, 2006 was $2.72. The total intrinsic value of options exercised during the six months ended June 30, 2006 was $40,482.

A summary of the status of the Company's nonvested shares issuable upon exercise of outstanding options as of June 30, 2006 and changes during the three and six month periods is presented below:

*(in thousands, except for weighted-average data)*

| Option Shares | Amount | 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 |

As of June 30, 2006, there was $7.0 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 2.4 years.

**Note 4 - Comprehensive Loss**

Total comprehensive loss was $14.7 million and $30.5 million for the three months and six months ended June 30, 2006, respectively, and $9.8 million and $19.1 and for the three and six months ended June 30, 2005. Total comprehensive loss consists of the net loss and unrealized gains and losses on marketable securities.

**Note 5 - 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. The primary component of Restricted Cash is a security deposit in the amount of $600,000 in the form of a letter of credit related to the lease agreement dated May 26, 2004 for office space in Warrington, Pennsylvania. The letter of credit is secured by cash and is recorded in the Company's balance sheets as "Restricted Cash." Beginning in March 2008, the security deposit and the letter of credit 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.

**Note 6 - Q2 2006 Restructuring Charge**

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

The workforce reduction totaled 52 employees, representing approximately 33% of the Company's workforce, and was focused primarily on its 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 over the past two fiscal quarters (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 includes $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain commercial programs. As of June 30, 2006, payments totaling $3.3 million had been made related to these items and $1.5 million were unpaid. Of the $1.5 million that was unpaid at June 30, 2006, $0.3 million was included in accounts payable and $1.2 million was included in accrued expenses, of which $0.8 million was classified as a current liability and $0.4 million was classified as long-term).

**Note 7 - 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 three or six months ended June 30, 2006 and June 30, 2005. However, as a result of the reductions in staff in the second quarter of 2006, 21,544 shares of unvested restricted stock awards were canceled and recorded as treasury stock.

**Note 8 -Litigation**

The following actions were filed in May 2006 in the United States District Court for the Eastern District of Pennsylvania against the Company and the Company's Chief Executive Officer, Robert J. Capetola: on May 1, 2006, by Hal Unschuld, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between December 28, 2005 and April 25, 2006; on May 8, 2006, by Michael Donuvich, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between December 28, 2005 and April 25, 2006; on May 9, 2006, by Raymond Lawrie, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between March 16, 2004 and April 25, 2006 (the "Lawrie Action"); and on May 15, 2006, Marilyn DePace, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between February 1, 2005 and April 24, 2006 (the "DePace Action"). In addition to the Company and Dr. Capetola, the Lawrie Action names the Company's Chief Financial Officer, John G. Cooper, and the DePace Action names the Company's former Chief Operating Officer, Christopher J. Schaber. Each of these actions generally alleges violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act in connection with various public statements made by the Company and seeks an order that the action may proceed as a class action and an award of compensatory damages in favor of the plaintiff and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On June 15, 2006, these actions were consolidated under the caption "In re: Discovery Laboratories Securities Litigation" and, in July 2006, the court appointed the Mizla Group to serve as lead plaintiff in these consolidated actions and the law firm of Chimicles & Tikellis LLP to act as lead counsel. The court also directed the lead plaintiff to file a consolidated amended complaint no later than August 7, 2006.

On May 16, 2005, Royal L. Knab filed a shareholder derivative complaint in the United States District Court for the Eastern District of Pennsylvania against the Company's Chief Executive Officer, Robert J. Capetola, and W. Thomas Amick, Antonio Esteve, Max E. Link and Herbert H. McDade, Jr., directors of the Company (the "Knab Action"). A second shareholder derivative complaint was filed on June 6, 2006 by Paul J. Squier, individually and on behalf of the Company, against the Company's Chief Executive Officer, Robert J. Capetola and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, directors of the Company, and Christopher J. Schaber, the Company's former Chief Operating Officer (the "Squier Action"). These actions generally allege violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, which were alleged to have occurred, in the Knab Action, from December 28, 2005 through the present, and, in the Squier Action, between 2005 and April 2006. The plaintiffs generally seek an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys's fees and costs. In July 2006, the Knab Action and the Squier Action were consolidated under the caption "In re: Discovery Laboratories Derivative Litigation." The parties have entered into a stipulation 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.

The Company intends to vigorously defend these actions. The potential impact of these actions, all of which are expected to 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 these proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

**Note 9 - 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 has received regulatory approval for marketing. Because 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;
- capital lease financings; and
- interest earned on invested capital.

Upon receiving a second Approvable Letter and experiencing the manufacturing issues that have caused the Company to modify its expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin, the market value of the Company's common stock declined, which has made it more difficult to obtain equity and debt financing on terms that would be beneficial to the Company in the long term. The Company has 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 considering multiple 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 before taking into account any strategic alternatives (including the potential restructuring of the Company's credit facility with PharmaBio Development Inc.), potential financings or amounts that may be potentially available through the CEFF, the Company believes that its current working capital is sufficient to meet planned activities into 2007. Under the CEFF, Kingsbridge is not obligated to purchase shares for any day during a draw-down when the volume weighted average price of the Company's common stock is below $2.00. Currently, the Company's common stock is trading below $2.00 per share and, therefore, the CEFF is not available to raise capital. If the Company's stock price rises above $2.00 per share, the Company would anticipate using the CEFF to support working capital needs in 2006 and 2007.

## 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, where 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 concluded patient enrollment for a Phase 2 clinical trial investigating the use of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. We are also developing Aerosurf, a proprietary SRT administered in aerosolized form, for the prevention and treatment of infants with respiratory distress. We are preparing to initiate Phase 2 clinical studies with Aerosurf administered through nasal continuous positive airway pressure (nCPAP), potentially obviating the need for endotracheal intubation and conventional mechanical ventilation.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, we recently completed and announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) and we are also developing our SRT to potentially address Acute Lung Injury (ALI), cystic fibrosis and other respiratory conditions.

Due to our previously-announced manufacturing issues, we have revised our expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. Further, as our manufacturing issues could not be resolved within the regulatory time frames mandated by the European Medicines Agency (EMEA), we have voluntarily withdrawn our Marketing Authorization Application (MAA) for Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. For a discussion of these events, 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. On May 4, 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. 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 RDS in premature infants in the United States, including preparing to respond to the second Approvable Letter and conducting a comprehensive investigation, analysis and remediation of our recent manufacturing issues;

- investing in development of SRT pipeline programs, primarily Aerosurf, which uses the aerosol generating technology rights licensed through a strategic alliance with Chrysalis Technologies (Chrysalis);

- use of our newly-acquired manufacturing facility, which is critical to the production of Surfaxin and our SRT clinical programs, to produce Surfaxin, other SRT formulations and aerosol development capabilities. We view our acquisition of this facility as an initial step in our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. Our strategy also includes, where appropriate, contracting with third-party manufacturers and building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products; and

- raising additional working capital and securing additional strategic partnerships for the development and commercialization of our proprietary SRT product candidates, including Surfaxin. We have recently 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 considering multiple alternatives including, but not limited to, potential business alliances, commercial and development partnerships, financings, business combinations and other similar opportunities, although no assurances are given that this evaluation will lead to any specific action or transaction.

Since our inception, we have incurred significant losses and, as of June 30, 2006, we had an accumulated deficit of $232.5 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities and, since 2005, 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, 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 June 30, 2006, we had: (i) cash and investments of $27.3 million; (ii) $47.8 million potentially available under the CEFF with Kingsbridge, subject to the terms and conditions of the agreement; (iii) a $9.0 million capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), of which an aggregate of $7.4 million has been drawn during the life of the facility and, after giving effect to principal payments, $5.2 million of which was still payable; and (iv) a secured revolving credit facility of $8.5 million with PharmaBio Development Inc. (PharmaBio), of which the entire amount is currently outstanding and due on December 31, 2006. 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 six months ended June 30, 2006 were $5.9 million and $13.5 million, respectively, and for the three and six months ended June 30, 2005 were $5.9 million and $11.0 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 reflects activities associated with research prior to the initiation of any potential human clinical trials. These 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 costs associated with operating our manufacturing facility in Totowa, New Jersey (which we acquired in December 2005), such as employee expenses, depreciation, the purchase of raw materials, quality control and assurance activities, and analytical services. In addition, manufacturing activities include expenses associated with our comprehensive investigation, analysis and remediation of our recent manufacturing issues, as well as 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.

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 six months ended June 30, 2006 and 2005:

| *( in thousands)* | **Three Months Ended June 30,** | | **Six Months Ended June 30,** | |
|---|---|---|---|---|
| **Research and Development Expenses:** | **2006**[1] | **2005** | **2006**[1] | **2005** |
| Research and pre-clinical operations | $ 560 | $ 426 | $ 1,068 | $ 1,355 |
| Manufacturing development | 2,892 | 2,656 | 5,391 | 4,046 |
| Unallocated development - clinical and regulatory operations | 2,007 | 1,845 | 4,537 | 3,484 |
| Direct clinical trial expenses | 452 | 937 | 2,528 | 2,099 |
| **Total Research and Development Expenses** | $ 5,911 | $ 5,864 | $ 13,524 | $ 10,984 |

(1) Included in expenses for the three and six months ended June 30, 2006 is a charge of $0.5 million and $0.9 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 is 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".

These factors include, but are not limited to:

- Completion of pre-clinical and clinical trials of our product candidates with the scientific results that support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant raw materials on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Obtaining corporate partnerships for the development of our SRT pipeline, including Surfaxin.
- Performance of our third-party collaborators on whom we rely for supply of raw materials and related services necessary to manufacture our SRT drug product candidates, including Surfaxin;
- Timely resolution of the CMC and cGMP-related matters at our manufacturing operations in New Jersey with respect to Surfaxin and our other SRTs presently under development, including matters that were noted by the FDA in its inspectional reports on Form FDA 483 and our recent drug stability testing issues;
- 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.
- Obtaining additional manufacturing operations, for which we presently have limited resources.

As a result of the amount and nature of these factors, many of which are outside our control, 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 for our products, we will not generate any revenues from the sale of our products and the value, financial condition and results of operations will be substantially harmed.

## CORPORATE PARTNERSHIP AGREEMENTS

**Chrysalis Technologies, a Division of Philip Morris USA Inc.**

In December 2005, we entered into a strategic alliance with Chrysalis Technologies (Chrysalis), a division of Philip Morris USA Inc., to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as ALI, neonatal respiratory failure, COPD, 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 neonatal intensive care unit (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 administered via nCPAP to treat premature infants in the NICU at risk for respiratory failure. 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 Acute Lung Injury (ALI).

**Laboratorios del Dr. Esteve, S.A.**

In December 2004, we reached an agreement with Esteve to restructure our pre-existing strategic alliance 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 Farmaceitici Spa (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution in Italy of Surfaxin.

## PLAN OF OPERATIONS

We have incurred substantial losses since inception and expects 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 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 Chemistry, Manufacturing and Controls (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 review, the FDA did not have any clinical or statistical comments. Also in April, ongoing analysis of data from Surfaxin process validation batches indicated that certain stability parameters had not been achieved. These process validation batches were manufactured as a requirement for our NDA and had been undergoing periodic stability testing.

We are completing our analysis of the second Approvable Letter and preparing a comprehensive information package for the FDA addressing the issues in the second Approvable Letter. Once we believe that we have resolved our Surfaxin manufacturing issues, including completing our comprehensive investigation covering among other things, manufacturing processes, test methods, and drug substance suppliers, we will request a meeting with the FDA and submit the comprehensive information package. Upon receipt of our request, procedurally, the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, we will seek to clarify the issues identified by the FDA in the second Approvable Letter and agree on a plan to obtain potential approval. Thereafter, to meet FDA regulatory requirements, we plan to manufacture new process validation batches and, once we have achieved satisfactory Surfaxin process validation and stability testing over an acceptable period (currently contemplated to be six-months), we will submit 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.

As a result of these events, we have revised our expectations concerning the timing of potential FDA approval of Surfaxin for the prevention of RDS in premature infants.

To address our manufacturing issues, we initiated a comprehensive investigation to determine the cause of the stability failure covering, among other things, manufacturing processes, test methods, and drug substance suppliers and, to date we have achieved the following progress:

- § We recently manufactured two “investigation batches” of Surfaxin that have passed all of the critical release specification assays, with the remaining release analytical procedures and stability monitoring ongoing. These investigation batches are intended to assess the impact of the investigative observations and will provide significant supportive data to a comprehensive investigation report and a corrective action and preventative action (CAPA) plan. These investigation batches are not designated as process validation batches, however.

- The data and information gathering phase of the investigation is nearly complete and we have begun to prepare the investigation report and the CAPA plan.

- We have been able, through the investigative process, to simultaneously address certain issues associated with the second Approvable Letter received from the FDA. We believe that resolution of the manufacturing issues and implementation of a CAPA plan will also resolve a number of issues raised by the FDA in the second Approvable Letter.

Dependent upon satisfactory completion of our investigation, we expect to meet with the FDA and manufacture new process validation batches in the fourth quarter of 2006.

We also filed an MAA with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. We received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA. We submitted a written response to all of the CHMP's outstanding issues in April 2006 and, subsequently met with the EMEA to discuss the response. Because our manufacturing issues could not be resolved within the regulatory time frames mandated by the EMEA, in June 2006 we determined to voluntarily withdraw the MAA for Surfaxin for the prevention and rescue treatment of RDS in premature infants.

*Surfaxin for BPD in Premature Infants*

On May 9, 2006, with enrollment totaling 136 patients, we determined to conclude our Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants. This double-blind, controlled Phase 2 clinical trial was intended to enroll up to 210 very low birth weight premature infants born at risk for developing BPD and its conclusion was related to cost-cutting measures and the potentially adverse effect that our manufacturing issues may have had on the near-term availability of Surfaxin drug product for this clinical trial. The study's objective is to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. In January 2006, the FDA granted Fast Track designation to Surfaxin for prevention and treatment of BPD in premature infants and, in October 2005, the Office of Orphan Products Development of the FDA (OOPD) granted Orphan Drug designation to Surfaxin for the treatment of BPD. In June 2006, the OOPD also granted Orphan Drug designation to Surfaxin for the prevention of BPD. We plan to perform a comprehensive analysis of the clinical data from this trial and report top-line results in the fourth quarter of 2006.

*Aerosurf, Aerosolized SRT*

Aerosurf is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failures. 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 anticipate initiating a pilot Phase 2 clinical study of Aerosurf utilizing the Chrysalis aerosolization technology in the first half of 2007. This timeline may be affected 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 Acute Respiratory Distress Syndrome (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 Acute Lung Injury (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 dispersion. 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 Pharma (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 enhanced 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. As of July 31, 2006, we have 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 indicated that certain stability parameters had not been achieved. These process validation batches were manufactured as a requirement for our NDA and had been undergoing periodic stability testing. To meet FDA regulatory requirements, following the meeting that we expect to have with the FDA, we expect to manufacture new process validation batches in the fourth quarter of 2006 and subject them to periodic stability testing over an acceptable period (currently contemplated to be six-months). As a result of these events, we have revised our expectations concerning the timing of potential FDA approval of Surfaxin for the prevention of RDS in premature infants. We are investing in manufacturing and regulatory activities intended to gain such FDA approval, including preparing our response to the second Approvable Letter and analysis and remediation of our recent manufacturing issues.

Longer-Term Manufacturing Capabilities

We view the acquisition of a 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 formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our New Jersey manufacturing operations is 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, NJ, facility, our long-term strategy includes 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 plan 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 June 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 June 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 carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of $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 six month periods ended June 30, 2006 was $14.7 million (or $0.24 per share) and $30.5 million (or $0.50 per share), respectively. The net loss for the three and six month periods ended June 30, 2005 was $9.8 million (or $0.18 per share) and $19.1 million (or $0.37 per share), respectively.

Included in the GAAP net loss for the quarter ender June 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 as a result of our revised expectations for the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Additionally, we adopted Financial Accounting Standards No. 123(R) ("FAS 123(R)") on January 1, 2006 using the modified prospective method, which resulted in the recognition of stock compensation expenses in the statement of operations during the three and six months ended June 30, 2006 without adjusting the prior year three and six month periods. The net loss for the three and six months ended June 30, 2006 includes $1.6 million (or $0.03 per share) and $3.2 million (or $0.05 per share), respectively, of stock-based compensation expenses as a result of our adoption of FAS 123(R). Excluding these charges, the net loss for the three and six months ended June 30, 2006 was $8.3 million (or $0.13 per share) and $22.5 million (or $0.37 per share), respectively.

**Revenues**

Revenue for the three and six months ended June 30, 2006 was $0 for both periods. Revenue for the three and six months ended June 30, 2005 was $24,000 and $85,000, 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 six months ended June 30, 2006 were $5.9 million and $13.5 million, respectively, and for the three and six months ended June 30, 2005 were $5.9 million and $11.0 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 increase as compared to the same prior year periods primarily reflects:

(i) manufacturing development activities (included in research and development expenses) to support the production of clinical and commercial drug supply for our SRT programs, including Surfaxin, SRT formulations and aerosol development capabilities, in conformance with current Good Manufacturing Practices (cGMPs). Expenses related to manufacturing development activities for the three and six months ended June 30, 2006 were $2.9 million and $5.4 million, respectively, as compared to $2.7 million and $4.0 million for the three and six months ended June 30, 2005, respectively. The increase in expenses 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 six months ended June 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 $3.0 million and $8.1 million for the three and six months ended June 30, 2006, respectively, as compared to $3.2 million and $7.0 million for the three and six months ended June 30, 2005, respectively. These costs are primarily associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and engineering of aerosol delivery systems, clinical trial implementation and management, clinical quality control and regulatory compliance activities, data management and biostatistics, including, among other things: (A) U.S. and European regulatory activities associated with Surfaxin for 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 $0.4 million and $0.6 million for the three and six months ended June, 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 six months ended June 30, 2006 were $4.0 million and $12.7 million, respectively, and for the three and six months June 30, 2005, were $4.1 million and $8.4 million, respectively. General and administrative expenses consist primarily of the costs of executive management, finance and accounting, business and commercial development, pre-launch commercial sales and marketing, legal, facility and other administrative costs.

The increase in general and administrative expenses as compared to the same prior year periods primarily reflects pre-launch commercial activities to build a United States commercial infrastructure in preparation for the previously anticipated commercial launch of Surfaxin in the second quarter of 2006. For the three and six months ended June 30, 2006, costs associated with these pre-launch commercial activities were $0.8 million and $5.5 million, respectively, as compared to $2.1 million and $4.4 million for the three and six months ended June 30, 2005, respectively. In April 2006, in connection with the second Approvable Letter and the failure of Surfaxin process validation batches to achieve certain stability parameters, which caused us to modify our expectations concerning the timing of potential FDA approval of Surfaxin, we discontinued pre-launch commercial activities and significantly downsized our commercial infrastructure. The cost associated with the discontinuance of such activities are a component of the Q2 2006 restructuring charge. Additionally, there is a charge of $1.1 million and $2.3 million for the three and six months ended June 30, 2006, respectively, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

**Q2 2006 Restructuring Charge**

In order to lower our cost structure and re-align our operations with business priorities, we reduced staff levels and reorganized corporate management. We took these actions as a result of receiving a second Approvable Letter and experiencing manufacturing issues that have caused us to modify our expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. The workforce reduction 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 over the past two fiscal quarters (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 includes $2.5 million of severance and benefits related to staff reductions and $2.3 million for the termination of certain commercial programs. As of June 30, 2006, payments totaling $3.3 million had been made related to these items and $1.5 million were unpaid. Of the $1.5 million that was unpaid at June 30, 2006, $0.3 million was included in accounts payable and $1.2 million was included in accrued expenses, of which $0.8 million was classified as a current liability and $0.4 million was classified as long-term).

**Other Income/(Expense)**

Other income and (expense) for the three and six months ended June 30, 2006 was $45,000 and $545,000, respectively, compared to $109,000 and $122,000 for the three and six months ended June 30, 2005.

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

Interest income for the three and six months ended June 30, 2006 $377,000 and $897,000, respectively, compared to $342,000 and $556,000 for the three and six months ended June 30, 2005. The increase is primarily due to a general increase in earned market interest rates.

Interest expense for the three and six months ended June 30, 2006 was ($332,000) and ($632,000), respectively, compared to ($233,000) and ($434,000) for the three and six months ended June 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;
- capital lease financings; and
- interest earned on invested capital.

Upon receiving a second Approvable Letter and experiencing manufacturing issues that have caused us to modify our expectations concerning the timing of potential FDA approval and commercial launch of Surfaxin for the prevention of RDS in premature infants, the market value of our common stock declined, which 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 considering multiple 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, we believe our current working capital is sufficient to meet planned activities into 2007, before taking into account any strategic alternatives, potential financings or amounts that may be potentially available through the CEFF. Under the CEFF, Kingsbridge is not obligated to purchase shares for any day during a draw-down when the volume weighted average price of our common stock is below $2.00. Currently, our common stock is trading below $2.00 per share and, therefore, the CEFF is not available to raise capital. If our stock price rises above $2.00 per share, we would anticipate using the CEFF 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, levels of resources that we devote to the further development of manufacturing and product development capabilities, technological advances, status of competitors, ability to establish collaborative arrangements 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 June 30, 2006, we had cash, cash equivalents, restricted cash and marketable securities of $27.3 million, as compared to $50.9 million as of December 31, 2005, a decrease of $23.6 million. The decrease primarily consists of cash used in operating and investing activities of $26.5 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.

**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.

This new 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 beginning on May 12, 2006. We are not obligated to utilize any of the $50 million available under the new 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)% |

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* 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. Kingsbridge is not obligated to purchase shares for any day during a draw-down when the VWAP on such day is below $2.00 per share. 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 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 of $2.03.

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 March 31, 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 treatment of RDS in premature infants and MAS 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 June 30, 2006, $8.5 million was outstanding under the credit facility and is classified as a current liability. The interest rate is the greater of 8% or prime rate plus 2% annually and payments are due quarterly in arrears. We are presently assessing a potential restructuring of this credit facility. Without such restructuring, principal and interest outstanding under this credit facility will be due and payable as a balloon payment on December 31, 2006.

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

Our primary capital lease financing arrangement is with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC). Under this arrangement, we purchase capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through this capital lease financing arrangement. The capital lease is secured by the related assets. Subject to certain conditions, this arrangement provides for financing of up to $9 million. On May 9, 2006, GECC agreed to amend the arrangement, which would have expired April 30, 2006, such that the funds are now available through October 2006**,** subject to certain conditions and in consideration of certain undertakings on our part, including a pledge of certain proceeds of certain components of our intellectual property and an agreement not to pledge, with certain exceptions, any interest in our intellectual property. 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 June 30, 2006, $5.2 million is outstanding ($1.9 million classified as current liabilities and $3.3 million as long-term liabilities) and $1.6 million remains available for future use, subject to certain conditions.

**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, NJ 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.

We also lease approximately 11,000 square feet of office and laboratory space in Doylestown, Pennsylvania. We maintain the Doylestown facility for the continuation of analytical laboratory activities under a lease that expires in August 2006, 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 and our capital lease financing arrangement with General Electric Capital Corporation, we have not entered into any additional arrangements to obtain additional financing.

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 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 and development 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

The following actions were filed in May 2006 in the United States District Court for the Eastern District of Pennsylvania against the Company and the Company's Chief Executive Officer, Robert J. Capetola: on May 1, 2006, by Hal Unschuld, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between December 28, 2005 and April 25, 2006; on May 8, 2006, by Michael Donuvich, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between December 28, 2005 and April 25, 2006; on May 9, 2006, by Raymond Lawrie, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between March 16, 2004 and April 25, 2006 (the "Lawrie Action"); and on May 15, 2006, Marilyn DePace, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between February 1, 2005 and April 24, 2006 (the "DePace Action"). In addition to the Company and Dr. Capetola, the Lawrie Action names the Company's Chief Financial Officer, John G. Cooper, and the DePace Action names the Company's former Chief Operating Officer, Christopher J. Schaber. Each of these actions generally alleges violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act in connection with various public statements made by the Company and seeks an order that the action may proceed as a class action and an award of compensatory damages in favor of the plaintiff and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief. On June 15, 2006, these actions were consolidated under the caption "In re: Discovery Laboratories Securities Litigation" and, in July 2006, the court appointed the Mizla Group to serve as lead plaintiff in these consolidated actions and the law firm of Chimicles & Tikellis LLP to act as lead counsel. The court also directed the lead plaintiff to file a consolidated amended complaint no later than August 7, 2006.

On May 16, 2005, Royal L. Knab filed a shareholder derivative complaint in the United States District Court for the Eastern District of Pennsylvania against the Company's Chief Executive Officer, Robert J. Capetola, and W. Thomas Amick, Antonio Esteve, Max E. Link and Herbert H. McDade, Jr., directors of the Company (the "Knab Action"). A second shareholder derivative complaint was filed on June 6, 2006 by Paul J. Squier, individually and on behalf of the Company, against the Company's Chief Executive Officer, Robert J. Capetola and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, directors of the Company, and Christopher J. Schaber, the Company's former Chief Operating Officer (the "Squier Action"). These actions generally allege violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, which were alleged to have occurred, in the Knab Action, from December 28, 2005 through the present, and, in the Squier Action, between 2005 and April 2006. The plaintiffs generally seek an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys's fees and costs. In July 2006, the Knab Action and the Squier Action were consolidated under the caption "In re: Discovery Laboratories Derivative Litigation." The parties have entered into a stipulation 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.

The Company intends to vigorously defend these actions. The potential impact of these actions, all of which are expected to 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 these proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

**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 Pharma, Inc. 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 current good manufacturing practices (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, analysis of ongoing stability data from Surfaxin process validation batches, which were produced as a requirement for our NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional process validation batches will likely have to be produced. We are presently conducting an investigation to determine the cause and define the corrective action and preventative action plan needed to potentially remediate these manufacturing issues. Our investigation covers, among other things, manufacturing processes, test methods, and drug substance suppliers. 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. We are preparing a comprehensive information package and, after we are satisfied that the manufacturing issues have been remediated, we will request a meeting with the FDA to discuss plans for the manufacture of new process validation batches and clarify the issues identified in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. At that time, the FDA will advise us of the time frame in which it will complete its review and advise us if it will accept our response to the second Approvable Letter as a complete response. After the FDA has accepted 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. In February 2006, we received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA. We submitted a written response to all of the CHMP's outstanding issues in April 2006 and subsequently met with the EMEA to discuss the response. Because our manufacturing issues could not be resolved within the regulatory time frames mandated by the EMEA, in June 2006, we determined to voluntarily withdrawn the MAA for Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. We intend to have further discussions with the EMEA and develop a strategy for potential Surfaxin approval 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, which contained a list of inspectional observations on Form FDA 483. Thereafter, we learned that analysis of ongoing stability data from Surfaxin "process validation batches", which are a part of our NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional Surfaxin process validation batches will likely have to be produced. These events have caused us to revise our expectations concerning the timing of potential FDA approval of our NDA. When we have completed and submitted our response to the second Approvable Letter and remediated our manufacturing issues, 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 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 causes 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. 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. The drug device products 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 manufacture the drug product devices to our specifications for use in clinical studies or commercialization. If we do not successfully identify and enter into a contractual agreement with drug device and components manufacturers, it will adversely affect development and commercialization of Aerosurf.

**If the parties we depend on for supplying our drug substance raw materials 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 drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and 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 that we expect will be produced by one or more manufacturers. We and our suppliers and vendors may not be able to (i) produce our drug substance, 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 vendors, 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 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 capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. Kingsbridge has the right under certain circumstances to terminate the CEFF, including as a consequence of a material adverse effect.

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 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 the Company.

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 National Market. See "Risk Factors: The market price of our stock may be adversely affected by market volatility."

**Our secured, revolving credit facility with PharmaBio is due on December 31, 2006. If we are unable to renegotiate the terms of the credit facility, payment of the outstanding principal and interest would significantly reduce our available working capital.**

As of June 30, 2006, we have $8.5 million outstanding under this credit facility. Outstanding principal and interest under this credit facility are due and payable as a balloon payment on December 31, 2006. We are currently assessing a potential restructuring of this credit facility. There is no assurance, however, that such a restructuring will be successful. If we are unable to restructure this credit facility, we expect to pay the outstanding principal and interest on December 31, 2006. Such a payment would significantly reduce our available working capital and our ability to implement our business strategy and could have a material adverse effect on and our business, results of operations and financial condition.

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

The issuance of shares of our common stock under the CEFFs 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 CEFFs 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 up to $47.8 million currently available under the CEFF. Under the CEFF, Kingsbridge is not obligated to purchase shares for any day during a draw-down when the volume weighted average price of our common stock is below $2.00. Currently, our common stock is trading below $2.00 per share and, therefore, the CEFF is not available to raise capital.

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 have determined that the establishment of a commercial infrastructure is 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, on May 4, 2006, we announced a reduction in the number of our employees and a reorganized corporate structure. The workforce reduction totaled 55 employees, representing approximately 34% 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. The duties and responsibilities of these executives have been transferred within the management organization and we presently do not expect to fill those positions in the near-term. 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 recently 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 June 30, 2006 we had 62,320,630 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 Warrant issued in connection with the 2004 CEFF and 12,167,047 shares of our common stock that are currently reserved for issuance under the CEFF. See “Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of June 30, 2006, up to 12,651,946, 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. Additional actions may be filed against the Company. Although we cannot predict the outcome of any of these 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

In the quarter ended June 30, 2006, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 2,333 shares of our common stock at an exercise prices of $1.53 per share for a aggregate consideration equal to $3,569. 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 quarter ended June 30, 2006 was $78,059, resulting in the issuance of 37,349 shares. There were no stock repurchases in the quarter ended June 30, 2006.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

At our annual meeting of the stockholders held on June 8, 2006 the following matters were voted on by the stockholders: (i) the election of five directors; (ii) the approval of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2006; and (iii) consideration and approval of an amendment to our Amended and Restated 1998 Stock Incentive Plan to increase the number of shares of our common stock available for issuance under the Amended and Restated 1998 Stock Incentive Plan by 1,200,000 shares. The results of such shareholder votes are as follows:

(i) Election of Directors

| | For | Withheld |
|---|---|---|
| W. Thomas Amick | 48,497,780 | 4,483,012 |
| Robert J. Capetola, Ph.D. | 47,725,666 | 5,255,126 |
| Antonio Esteve, Ph.D. | 45,461,662 | 7,519,130 |
| Max Link, Ph.D. | 47,523,620 | 5,457,172 |
| Herbert H. McDade, Jr. | 47,500,970 | 5,479,822 |
| Marvin E. Rosenthale, Ph.D | 47,548,850 | 5,431,942 |

(ii) Approval of Ernst & Young LLP as the Independent Company's Registered Public Accounting Firm

| For | Against | Abstain |
|---|---|---|
| 51,786,483 | 942,901 | 251,408 |

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

| For | Against | Abstain | Withheld |
|---|---|---|---|
| 15,204,099 | 8,841,704 | 180,595 | 28,754,394 |

**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: August 9, 2006

By: /s/ Robert J. Capetola, Ph.D.

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

Date: August 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 | $8,500,000 Amended and Restated Promissory Note, amended and restated as of November 3, 2004, by and between Discovery and PharmaBio Development Inc. | Incorporated by reference to Exhibit 4.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004. |
| 4.9 | 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. |
| 4.10 | 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. |
| 10.1 | Common Stock Purchase Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited. | Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006. |
| 10.2* | Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert J. Capetola, Ph.D. | Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |
| 10.3* | Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and John G. Cooper | Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |
| 10.4* | Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and David L. Lopez, Esq., CPA | Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |
| 10.5* | Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert Segal, M.D., F.A.C.P. | Incorporated by reference to Exhibit 10.4 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |
| 10.6* | Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Kathryn A. Cole | Incorporated by reference to Exhibit 10.5 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |
| 10.7 | Amendment No.4, dated as of May 9, 2006, to the Master Security Agreement between General Electric Capital Corporation and Discovery. | Incorporated by reference to Exhibit 10.8 to Discovery's Current Report on Form 10-Q, as filed with the SEC on May 10, 2006. |

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 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. |

Exhibit 31.1

CERTIFICATIONS

I, Robert J. Capetola, certify that:

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

2. Based on my knowledge, this 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: August 9, 2006

By: /s/ Robert J. Capetola

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

Exhibit 31.2

CERTIFICATIONS

I, John G. Cooper, certify that:

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

2. Based on my knowledge, this 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: August 9, 2006

By: /s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer

Exhibit 32.1

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 June 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: August 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.