

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

FORM 10-Q

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

For the quarterly period ended June 30, 2007

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-26422

**DISCOVERY LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-3171943**

(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 xNO

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  Accelerated filer  Non-accelerated filer

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

As of August 7, 2007, 84,636,997 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc., 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 (Exchange Act). 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. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; implementation of a corrective action and preventive plan (CAPA), including the manufacture of investigational batches, and remediation of manufacturing issues related to the April 2006 process validation stability failures and plans with respect to the release and stability testing of recently manufactured new process validation batches of Surfaxin<sup>®</sup>; plans regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

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 that 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 we may not successfully develop and market our products, and even if we do, we may not become profitable;
- risks relating to the progress of our research and development;
- risks relating to significant, time-consuming and costly research and development efforts, including pre-clinical studies, clinical trials and testing, and the risk that clinical trials may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for any products that we may develop, independently, with our development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we file or limit such applications to particular indications or apply other label limitations;
- risks that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;
- risks that we will not timely and successfully resolve the Chemistry, Manufacturing and Controls (CMC) and current Good Manufacturing Practices-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other Surfactant Replacement Therapies (SRT) presently under development, including those identified in connection with our process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- risks that the CMC section of our NDA will not satisfy the FDA;
- risks relating to our own drug manufacturing operations and the drug manufacturing operations of our third-party suppliers and contract manufacturers;
- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and aerosolization systems and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;

- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully manufacture and commercialize products that combine our drug products with innovative aerosolization technologies;
- risks that financial market conditions may change, additional financings could result in equity dilution, or we will be unable to maintain the Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;
- the risk that we will not be able to raise additional capital or enter into additional strategic alliances and collaboration arrangements (including strategic alliances in support of our aerosol and other SRT);
- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- risks relating to our ability to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all;
- the risk that we or our marketing partners will not succeed in developing market awareness of our products;
- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- risks relating to the maintenance, protection and expiry of the patents and licenses related to our SRT and the potential development of competing therapies and/or technologies by other companies;
- risks relating to the impact of securities, product liability, and other litigation or claims that have been and may be brought against us and our officers and directors;
- risks relating to reimbursement and health care reform; and
- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this report.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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,<br>2007<br>(Unaudited) | December 31,<br>2006 |
|---|---------------------------------|----------------------|
| <b>ASSETS</b>   |                                 |                      |
| Current Assets:   |                                 |                      |
| Cash and cash equivalents   | \$ 21,495                       | \$ 26,173            |
| Restricted cash   | 647                             | 829                  |
| Available-for-sale marketable securities  | 18,611                          | --                   |
| Prepaid expenses and other current assets   | 779                             | 565                  |
| <b>Total Current Assets</b>   | <b>41,532</b>                   | <b>27,567</b>        |
| Property and equipment, net   | 5,618                           | 4,794                |
| Deferred financing costs and other assets   | 1,924                           | 2,039                |
| <b>Total Assets</b>   | <b>\$ 49,074</b>                | <b>\$ 34,400</b>     |
| <b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>   |                                 |                      |
| Current Liabilities:  |                                 |                      |
| Accounts payable and accrued expenses   | \$ 6,184                        | \$ 5,953             |
| Capitalized leases and note payable, current portion  | 1,758                           | 2,015                |
| <b>Total Current Liabilities</b>  | <b>7,942</b>                    | <b>7,968</b>         |
| Loan payable, non-current portion, including accrued interest   | 9,268                           | 8,907                |
| Capitalized leases and note payable, non-current portion  | 2,487                           | 2,687                |
| Other liabilities   | 966                             | 516                  |
| <b>Total Liabilities</b>  | <b>20,663</b>                   | <b>20,078</b>        |
| Stockholders' Equity:   |                                 |                      |
| Common stock, \$0.001 par value; 180,000 shares authorized;<br>84,947 and 69,871 shares issued; and 84,634 and 69,558 shares<br>outstanding at June 30, 2007 and December 31, 2006, respectively. | 85                              | 70                   |
| Additional paid-in capital  | 298,361                         | 265,604              |
| Accumulated deficit   | (266,992)                       | (248,298)            |
| Treasury stock (at cost); 313 shares  | (3,054)                         | (3,054)              |
| Other comprehensive income  | 11                              | --                   |
| <b>Total Stockholders' Equity</b>   | <b>28,411</b>                   | <b>14,322</b>        |
| <b>Total Liabilities &amp; Stockholders' Equity</b>   | <b>\$ 49,074</b>                | <b>\$ 34,400</b>     |

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<br>June 30, |                    | Six Months Ended<br>June 30, |                    |
|---|--------------------------------|--------------------|------------------------------|--------------------|
|   | 2007                           | 2006               | 2007                         | 2006               |
| Revenue   | \$ -                           | \$ -               | \$ -                         | \$ -               |
| Expenses:   |                                |                    |                              |                    |
| Research and development  | 6,794                          | 5,911              | 12,216                       | 13,524             |
| General and administrative  | 3,465                          | 4,024              | 6,219                        | 12,706             |
| Restructuring charge  | --                             | 4,805              | --                           | 4,805              |
| Total expenses  | <u>10,259</u>                  | <u>14,740</u>      | <u>18,435</u>                | <u>31,035</u>      |
| Operating loss  | (10,259)                       | (14,740)           | (18,435)                     | (31,035)           |
| Other income / (expense):   |                                |                    |                              |                    |
| Interest and other income   | 559                            | 377                | 865                          | 1,177              |
| Interest and other expense  | (684)                          | (332)              | (1,124)                      | (632)              |
| Other income / (expense), net   | <u>(125)</u>                   | <u>45</u>          | <u>(259)</u>                 | <u>545</u>         |
| Net loss  | <u>\$ (10,384)</u>             | <u>\$ (14,695)</u> | <u>\$ (18,694)</u>           | <u>\$ (30,490)</u> |
| Net loss per common share -   |                                |                    |                              |                    |
| Basic and diluted   | \$ (0.12)                      | \$ (0.24)          | \$ (0.24)                    | \$ (0.50)          |
| Weighted average number of common<br>shares outstanding - basic and diluted | 83,825                         | 61,652             | 76,907                       | 61,411             |

See notes to consolidated financial statements

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

|   | <b>Six Months Ended</b> |                  |
|---|-------------------------|------------------|
|   | <b>June 30,</b>         |                  |
|   | <u>2007</u>             | <u>2006</u>      |
| Cash flows from operating activities:                                       |                         |                  |
| Net loss  | \$ (18,694)             | \$ (30,490)      |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |                  |
| Depreciation and amortization   | 781                     | 448              |
| Stock-based compensation and 401(k) match                                   | 2,589                   | 3,757            |
| Loss on disposal of property and equipment                                  | 3                       | --               |
| Changes in:   |                         |                  |
| Prepaid expenses and other assets   | (222)                   | 212              |
| Accounts payable and accrued expenses                                       | 231                     | (337)            |
| Other assets  | (159)                   | 1                |
| Other liabilities and accrued interest on loan payable                      | 811                     | 440              |
| Net cash used in operating activities                                       | <u>(14,660)</u>         | <u>(25,969)</u>  |
| Cash flows from investing activities:                                       |                         |                  |
| Purchase of property and equipment  | (1,326)                 | (709)            |
| Restricted cash   | 182                     | (15)             |
| Purchases of marketable securities  | (20,483)                | (4,631)          |
| Proceeds from sales or maturity of marketable securities                    | 1,883                   | 7,884            |
| Net cash (used in) / provided by investing activities                       | <u>(19,744)</u>         | <u>2,529</u>     |
| Cash flows from financing activities:                                       |                         |                  |
| Proceeds from issuance of securities, net of expenses                       | 30,183                  | 2,783            |
| Equipment financed through capital lease obligation                         | 4,245                   | 1,036            |
| Principal payments under capital lease obligation                           | (4,702)                 | (762)            |
| Net cash provided by financing activities                                   | <u>29,726</u>           | <u>3,057</u>     |
| Net decrease in cash and cash equivalents                                   | (4,678)                 | (20,383)         |
| Cash and cash equivalents - beginning of period                             | 26,173                  | 47,010           |
| Cash and cash equivalents - end of period                                   | <u>\$ 21,495</u>        | <u>\$ 26,627</u> |
| Supplementary disclosure of cash flows information:                         |                         |                  |
| Interest paid   | \$ 344                  | \$ 619           |
| Non-cash transactions:  |                         |                  |
| Unrealized gain/(loss) on marketable securities                             | 11                      | 2                |

See notes to consolidated financial statements

**Note 1 - The Company and Basis of Presentation**

**The Company**

Discovery Laboratories, Inc. (referred to in these Notes as “we”, “us” and “our”) is a biotechnology company developing our proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory disorders and 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), Pediatric Intensive Care Unit (PICU), critical care unit (ICU) and other hospital settings, to treat conditions for which there are few or no approved therapies available.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. We filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, we received a second Approvable Letter from the FDA in connection with this NDA. We are also developing Surfaxin for other neonatal and pediatric respiratory conditions and disorders, such as Bronchopulmonary Dysplasia (BPD) and Acute Respiratory Failure (ARF). Aerosurf™ is our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU and PICU, we believe that our SRT will also potentially address a variety of debilitating respiratory conditions affecting other pediatric, young adult and adult patients in the ICU and other hospital settings, such as Acute Lung Injury (ALI), cystic fibrosis, chronic obstructive respiratory disorder (COPD), asthma, Acute Respiratory Distress Syndrome (ARDS) and other debilitating respiratory conditions.

We have implemented a business strategy that includes: (i) actions intended to gain regulatory approval for Surfaxin for the prevention of RDS in premature infants in the United States; (ii) continued investment in development of SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in enhancements to our quality systems and manufacturing capabilities, including our operations in Totowa, NJ (which we acquired in December 2005), to produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin and our other SRT product candidates, and potentially to develop new and enhanced formulations of Surfaxin and our other SRT product candidates. Our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities for the production of our precision-engineered SRT drug products; and (iv) seeking investments of additional capital including potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our 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 periods ended June 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. Certain prior period balances have been reclassified to conform to the current period presentation. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2006.



## **Note 2 - Accounting Principles and Recent Accounting Pronouncements**

### *Accounting Principles*

There have been no changes to our critical accounting policies since December 31, 2006. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2006. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

### *Recent Accounting Pronouncements*

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the consolidated financial statements.

## **Note 3 - Net Loss Per Share**

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

## **Note 4 - Comprehensive Loss**

Total comprehensive loss was \$10.4 million and \$18.7 million for the three months and six months ended June 30, 2007, respectively, and \$14.7 million and \$30.5 million for the three months and six months ended June, 2006. 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 we disclose such amounts separately on our balance sheets. The primary component of Restricted Cash is a cash security deposit in the amount of \$600,000 securing a letter of credit in the same amount related to our lease agreement dated May 26, 2004 for office space in Warrington, Pennsylvania. Beginning in March 2010, the security deposit and the letter of credit related to the lease agreement will be reduced to \$400,000 and will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease in February 2013, the letter of credit will expire.

## **Note 6 - Stock Based Employee Compensation**

We have a stock-based employee compensation plan that is intended to attract, retain and provide incentives for employees, officers and directors, and to align stockholder and employee interests. We use the Black-Scholes option pricing model to determine the fair value of stock options and amortize the stock-based compensation expense over the requisite service periods of the stock options. The fair value of the stock options is determined on the date of grant using the Black-Scholes option-pricing model. The fair value of stock options is affected by our stock price and several subjective variables, including the expected stock price volatility over the term of the option, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

We use historical data and other factors to estimate the expected term, volatility and forfeiture rates within the valuation model. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant. We have not and do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model. We estimate forfeitures of unvested stock options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates, resulting in recognition of stock-based compensation expense only for those options that vest.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing formula and the assumptions noted in the following table:

|                     | June 30, 2007 | June 30, 2006 |
|---------------------|---------------|---------------|
| Expected volatility | 97%           | 101%          |
| Expected term       | 4 & 5 years   | 5 years       |
| Risk-free rate      | 4.6%          | 5.0%          |
| Expected dividends  | --            | --            |

The total employee stock-based compensation for the three and six months ended June 30, 2007 and 2006 was as follows:

|                          | Three Months Ended<br>June 30, |                 | Six Months Ended<br>June 30, |                 |
|--------------------------|--------------------------------|-----------------|------------------------------|-----------------|
|                          | 2007                           | 2006            | 2007                         | 2006            |
| Research & Development   | \$ 555                         | \$ 516          | \$ 789                       | \$ 903          |
| General & Administrative | 1,182                          | 1,038           | 1,607                        | 2,311           |
| <b>Total</b>             | <b>\$ 1,737</b>                | <b>\$ 1,554</b> | <b>\$ 2,396</b>              | <b>\$ 3,214</b> |

As of June 30, 2007, there was \$8.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.07 years.

### Note 7 - Working Capital

Cash is required to fund our working capital needs, to purchase capital assets, and to pay 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 operations, clinical trials and research and development efforts until such time, if ever, that one of our products receives regulatory approval for marketing and begins to generate sales. Since we have not generated any revenue from the sale of any products, we have primarily relied upon the capital markets and debt financings as our primary sources of funding. We will continue to be opportunistic in accessing the capital markets to obtain financing on terms satisfactory to us. We plan to fund our future cash requirements through:

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

After taking into account the registered direct public offering in April 2007 that generated gross proceeds of \$30.2 million (\$28.1 million net), and before taking into account any amounts that may be potentially available through our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources"), any potential strategic collaborations, and any potential financings, we believe that our current working capital is sufficient to meet planned activities into mid 2008. Use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of common stock that we may issue under the CEFF (not more than approximately 7.1 million shares as of June 30, 2007). In addition, during the eight trading day pricing period for a draw down, if the volume weighted average price of our common stock (VWAP) for any one trading day is less than the greater of (i) \$2.00 or (ii) 85 percent of the closing price of 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 that we had initially specified. We anticipate using the CEFF, when available, to support working capital needs in 2007.

## Note 8 - Q2 2006 Restructuring Charge

In April 2006, we received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants and announced that ongoing analysis of data from Surfaxin process validation batches that we had manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. As a result, to lower our cost structure and re-align our operations with changed business priorities, in April 2006, we reduced our staff levels and reorganized corporate management. 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 No. 146 "Accounting for Costs Associated with Exit or Disposal Activities".

As of June 30, 2007, the remaining balance of the unpaid restructuring charge was \$0.6 million, of which \$0.5 million was included in accounts payable and accrued expenses and \$0.1 million was classified as a long-term liability.

## Note 9 - Debt

### Capital Equipment Financing Arrangements

On May 21, 2007, we and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. (Merrill Lynch), entered into a Credit and Security Agreement (Loan Agreement), pursuant to which Merrill Lynch is providing us \$12.5 million credit facility (Facility) to fund our capital programs. Under the Facility, \$9 million was immediately available with up to an additional \$3.5 million becoming available, at a rate of \$1 million for each \$10 million raised by us through business development partnerships, stock offerings and other similar financings. Approximately \$4 million of the Facility has been drawn to fund the prepayment (GECC Pay Down) of all our outstanding indebtedness to General Electric Capital Corporation (GECC) under the Master Security Agreement with GECC dated December 20, 2002, as amended (GECC Agreement). The right to draw funds under the Facility will expire on May 30, 2008, subject to a best efforts undertaking by Merrill Lynch to extend the draw down period beyond the expiration date for an additional six months. The minimum advance under the Facility is \$100,000. Interest on each advance will accrue at a fixed rate per annum equal to LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances will be payable in equal installments on the first business day of each month. We may prepay advances, in whole or in part, at any time, subject to a prepayment penalty, which, depending on the period of time elapsed from the closing of the Facility, will range from 4% to 1%.

We may use the Facility to finance (a) new property and equipment and (b) up to approximately \$1.7 million "Other Equipment" and related costs, which may include leasehold improvements, intangible property such as software and software licenses, specialty equipment, a pre-payment penalty which was paid to GECC and "soft costs" related to financed property and equipment (including, without limitation, taxes, shipping, installation and other similar costs). Advances to finance the acquisition of new property and equipment will be amortized over a period of 36 months. The advance related to the GECC Pay Down will be amortized over a period of 27 months and Other Equipment and related costs will be amortized over a period of 24 months.

Our obligations to Merrill Lynch are secured by a security interest in (a) the property and equipment financed by us under the Facility, including the property and equipment securing GECC at the time of the GECC Pay Down, and (b) all of our intellectual property, subject to limited exceptions set forth in the Loan Agreement (Supplemental Collateral). The Supplemental Collateral will be released on the earlier to occur of (i) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (ii) the date on which we shall have maintained over a continuous 12-month period ending on or after March 31, 2008, measured at the end of each calendar quarter, a minimum cash balance equal to our projected cash requirements for the following 12-month period. In addition, we, PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), to which we are indebted under a separate loan arrangement (discussed below), and Merrill Lynch entered into an Intercreditor Agreement under which Merrill Lynch has agreed to subordinate its security interest in the Supplemental Collateral (which does not include all financed property and equipment) to the security interest in the same collateral that we previously granted to PharmaBio.

As of June 30, 2007, \$4.2 million was outstanding under the secured credit facility with Merrill Lynch and \$4.8 million remained available for use, subject to the conditions of the Facility.

Loan with PharmaBio Development, Inc. d/b/a/ NovaQuest (PharmaBio), a strategic investment group of Quintiles Transnational Corp.

We have a loan with PharmaBio in the principal amount of \$8.5 million that matures on April 30, 2010. Interest on the loan accrues at the prime lending rate, subject to change when and as such rate changes, compounded annually, and is payable on the maturity date of the loan. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. As of June 30, 2007, \$9.3 million was outstanding on this loan, which was comprised of \$8.5 million of principal and \$0.8 million of accrued and unpaid interest. For further discussion, see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

**Note 10 - Litigation**

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various of our public statements. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs 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 April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania. Plaintiffs filed an opening brief on July 2, 2007 and defendants filed their opening brief on August 6, 2007. Plaintiffs must file their reply brief on August 20, 2007.

On May 1, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the consolidated shareholder derivative complaint that was filed on December 29, 2006 under the caption "In re: Discovery Laboratories Derivative Litigation." The complaint named as defendants our Chief Executive Officer, Robert J. Capetola, four of our outside directors - Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, and Christopher J. Schaber, our former Chief Operating Officer, and sought an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. Although they were granted leave to file a second amended complaint by May 15, 2007, plaintiffs did not re-file. As the period during which an appeal may be filed has expired, this matter is concluded.

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

We have from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination in 2006 of certain pre-launch commercial programs following our process validation stability failure. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, we believe the pending matters are unlikely to have a material adverse effect on our financial condition or results of operations. However, there can be no assurance that we will be successful in any proceeding to which we are or may be a party.

## 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 disorders and 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 SRT 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), Pediatric Intensive Care Unit (PICU), critical care unit (ICU) and other hospital settings, where there are few or no approved therapies available.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed a NDA with the FDA for our lead product, Surfaxin® (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, we received a second Approvable Letter from the FDA in connection with this NDA. For older children being treated in the PICU, we recently initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from ARF. We are also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf™ is our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU and PICU, we believe that our SRT will also potentially address a variety of debilitating respiratory conditions affecting other pediatric, young adult and adult patients in the ICU and other hospital settings, such as Acute Lung Injury (ALI), cystic fibrosis, chronic obstructive respiratory disorder (COPD), asthma, Acute Respiratory Distress Syndrome (ARDS) and other debilitating respiratory conditions.

We have implemented a business strategy that includes:

- actions intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, including (i) finalizing and submitting our response to the April 2006 Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA; and (ii) completing analysis and remediation of manufacturing issues related to the April 2006 process validation stability failure;
- continued investment in the development of our SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);
- continued investment in enhancements to our quality systems and our manufacturing capabilities, including our operations in Totowa, NJ (which we acquired in December 2005). We plan to (i) produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial needs of Surfaxin and our other SRT product candidates, and (ii) potentially develop new and enhanced formulations of Surfaxin and our other SRT product candidates. Our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities for the production of our precision-engineered SRT drug products; and

- seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. We continue to evaluate a variety of strategic transactions intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

Since our inception, we have incurred significant losses and, as of June 30, 2007, we had an accumulated deficit of \$267.0 million. The majority of our expenditures to date have been for and in support of research and development activities. 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, 2007, we had: (i) cash of \$40.8 million; (ii) approximately 7.1 million shares potentially available for issuance under our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, for future financings (not to exceed \$40.5 million), subject to certain conditions that could cause the CEFF to be unavailable (discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources”); (iii) \$9.3 million outstanding (\$8.5 million principal and \$0.8 million of accrued interest as of June 30, 2007) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp. (Quintiles), which is due and payable together with all accrued interest on April 30, 2010; and (iv) \$4.2 million debt outstanding under a \$12.5 million capital equipment financing arrangement with Merrill Lynch Capital, of which \$4.0 million was applied to prepay the outstanding capital equipment loan and prepayment penalties then due to General Electric Capital Corporation (GECC). 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, 2007 were \$6.8 million and \$12.2 million, respectively. Research and development expenses for the three and six months ended June 30, 2006 were \$5.9 million and \$13.5 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, formulation development, manufacturing development, clinical and regulatory operations and other direct preclinical and clinical projects.

These cost categories typically include the following expenses:

### Manufacturing Development

Manufacturing development primarily reflects costs incurred to develop current good manufacturing practices (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Manufacturing development activities include: (1) costs associated with our manufacturing operations in Totowa, NJ (which we acquired from our then-contract manufacturer, Laureate Pharma, Inc. (Laureate) in December 2005) to support the production of clinical and anticipated commercial drug supply for our SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; (2) continued investment in our quality assurance and analytical chemistry capabilities, including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding and upgrading our quality operations to meet production needs for our SRT pipeline in accordance with cGMP; and (3) expenses associated with our comprehensive investigation of the April 2006 Surfaxin process validation stability failure and remediation of our related manufacturing issues and activities associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter.

## Unallocated Development - Clinical, Regulatory and Formulation Development Operations

Clinical, regulatory and formulation development operations reflect the preparation, implementation and management of our clinical trial activities in accordance with current good clinical practices (cGCPs) and research and development of aerosolized and other related formulations of our precision-engineered lung surfactant, engineering of aerosol delivery systems and analytical chemistry activities to support the continued development of Surfaxin. Included in unallocated clinical, regulatory and formulation development 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, including such activities associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter.

### Direct Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include pre-clinical activities associated with the development of SRT formulations prior to the initiation of any potential human clinical trials and activities associated with conducting clinical trials, including 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 each of the foregoing categories for the three and six months ended June 30, 2007 and 2006:

| <i>( in thousands)</i>                                       | Three Months Ended<br>June 30, |                 | Six Months Ended<br>June 30, |                  |
|--|--------------------------------|-----------------|------------------------------|------------------|
|  | 2007                           | 2006            | 2007                         | 2006             |
| <b>Research and Development Expenses:</b>                    |                                |                 |                              |                  |
| Manufacturing development                                    | \$ 2,930                       | \$ 2,892        | \$ 5,267                     | \$ 5,391         |
| Unallocated development - clinical and regulatory operations | 2,307                          | 2,007           | 4,335                        | 4,537            |
| Direct pre-clinical and clinical program expenses            | 1,557                          | 1,012           | 2,614                        | 3,596            |
| <b>Total Research &amp; Development Expenses</b>             | <b>\$ 6,794</b>                | <b>\$ 5,911</b> | <b>\$ 12,216</b>             | <b>\$ 13,524</b> |

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

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical or pre-clinical development. The status and anticipated completion date of each of our lead SRT programs are discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations." 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 "Risk Factors" section herein and those contained in our most recent Annual Report on Form 10-K.

Development risk factors include, but are not limited to:

- Completion of pre-clinical and clinical trials of our SRT product candidates with scientific results that are sufficient to support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant active drug substances on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;

- Performance of our third-party collaborators and suppliers on whom we rely for supply of drug substances, medical device components and related services necessary to manufacture our SRT drug product candidates, including Surfaxin and Aerosurf;
- Timely and successful resolution of the CMC and cGMP-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other SRT presently under development, including those matters identified in connection with the April 2006 process validation stability failures and those noted by the FDA in its 2005 and 2006 inspectional reports on Form FDA 483;
- Successful manufacture at our manufacturing operations in Totowa, NJ of our SRT drug product candidates, including Surfaxin;
- Successful development and implementation of a manufacturing strategy for the Chrysalis aerosolization device and related materials to support clinical studies and commercialization of Aerosurf; and
- Providing for additional manufacturing capabilities, for which we presently have limited resources.

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

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

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

## **CORPORATE PARTNERSHIP AGREEMENTS**

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

In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as neonatal respiratory failure, ALI, cystic fibrosis, COPD, asthma, and others. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to deliver therapeutics to the deep lung.

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

The alliance focuses on therapies for hospitalized patients, including those in the NICU, PICU and 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 combination 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 aerosolization device platform, disposable dose packets and patient interface. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination drug-device products. We have exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Generally, Chrysalis will receive a tiered royalty on product sales: the base royalty generally applies to aggregate net sales of less than \$500 million per contract year; the royalty generally increases on aggregate net sales in excess of \$500 million per contract year, and generally increases further on aggregate net sales of alliance products in excess of \$1 billion per contract year.



Our lead neonatal program utilizing the Chrysalis technology is Aerosurf, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. We are also planning an adult program utilizing the Chrysalis aerosolization technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI and will be assessing the timing for implementation of our adult program in late 2007.

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

In December 2004, we further restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. We had first entered into the alliance in 1999 and had revised it in 2002 to broaden the territory to include all of Europe, Central and South America, and Mexico. Under the 2004 revision, we regained full commercialization rights to our SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults, in key European markets, Central America, and South America. 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. We also agreed to pay to Esteve 10% of cash up-front and milestone fees (not to exceed \$20 million in the aggregate) that we may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain other SRTs in the territory for which we had previously granted a license to Esteve. Esteve has agreed to make stipulated cash payments to us upon our 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 Dompé farmaceutici s.p.a. (Dompé), a privately owned Italian company. Under the sublicense agreement, Dompé will be responsible for sales, marketing and distribution of Surfaxin in Italy.

#### **PLAN OF OPERATIONS**

We have incurred substantial losses since inception and expect to continue to expend substantial amounts for continued product research, development, manufacturing, and general business activities. We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability.

Through June 30, 2007, 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 collaboration and other 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, 2007, we had not generated taxable income. At December 31, 2006, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$229.8 million. The future utilization of such loss carryforward may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we had a research and development tax credit carryforward of \$5.2 million at December 31, 2006. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 through 2026.

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. See “Management’s Discussion and Analysis - Research and Development.”

Our major research and development projects include:

### SRT for Neonatal and Pediatric Indications

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

#### *Surfaxin for the Prevention of RDS in Premature Infants*

In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested information primarily focused on the CMC section of our NDA, predominately involving drug product specifications and stability, analytical methods and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our contract manufacturer, Laureate Pharma, Inc. (Laureate) as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately conducted a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to identify a most probable root cause, and executed a corrective action and preventative action (CAPA) plan. As part of our comprehensive investigation, we manufactured a series of investigational batches that are being monitored using our most predictive stability-indicating method. These batches, which are not designated process validation batches for the NDA and are intended to provide data to support the CAPA, continue to demonstrate acceptable stability, with the earliest manufactured batches demonstrating acceptable stability through twelve months, and the most-recently manufactured batches, through six months.

In December 2006, we attended a meeting with the FDA, the purpose of which was to clarify certain of the key CMC matters identified by the FDA in the Approvable Letter, provide information concerning the status and interim findings of our comprehensive investigation into the process validation stability failure and efforts to remediate the related manufacturing issues, and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. Following that meeting and consistent with the guidance from the FDA, in February 2007, we completed the manufacture of three new Surfaxin process validation batches. These process validation batches are subjected to ongoing comprehensive stability testing on pre-specified testing dates, initially every three months, in accordance with an established protocol that complies with guidelines established by the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use). Under our comprehensive testing protocol, these process validation batches have demonstrated acceptable stability through three months and continue to be monitored. The process validation batches must demonstrate acceptable stability under our comprehensive testing protocol through six-months before we can file our formal response to the Approvable Letter. We anticipate that six-month stability data will be available in October and, if these process validation batches demonstrate acceptable stability at that time, we plan to file our formal response to the Approvable Letter in the October 2007 timeframe. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants.

In June 2006, we voluntarily withdrew the Marketing Authorization Application (MAA) filed in October 2004 with the European Medicines Agency (EMA) for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMA procedure. Our withdrawal of the MAA precluded final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials, which had been the focus of a recent EMA clinical expert meeting and were expected to be reviewed at a planned Oral Explanation before the Committee for Medicinal Products for Human Use (CHMP) in late June 2006. We plan in the future to have further discussions with the EMA and develop a strategy to potentially gain approval for Surfaxin in Europe.

#### *Surfaxin for BPD in Premature Infants*

In October 2006, we announced preliminary results of our Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD and anticipate determining the next development steps for this program in late 2007 or early 2008.

#### *Surfaxin for Acute Respiratory Failure*

In June 2007, we initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from ARF. This Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care with sham air control. Approximately 180 children under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 20 sites throughout the United States, Chile, and Europe. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. The trial is expected to be completed by mid-year 2008.

#### *Aerosurf, Aerosolized SRT*

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 (Aeroneb Pro®) 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.

We are presently collaborating with Chrysalis on the development of a prototype aerosolization system to deliver Aerosurf to patients in the NICU. We have also met with and received guidance from the FDA with respect to the design of a proposed Phase 2 clinical program utilizing Chrysalis' technology. We and Chrysalis, together with third-party engineers and manufacturers, are presently collaborating on the development and optimization of this novel system as well as next generation drug device systems. The initial prototype development work, originally expected to be completed in the second half of 2007, is now anticipated to be completed in the first quarter of 2008. Accordingly, initiation of our Phase 2 clinical program is now anticipated in the first quarter of 2008. See "*Surfaxin for the Prevention of RDS in Premature Infants,*" above.

### SRT for Critical Care and Hospital Indications

#### *Surfaxin for Acute Respiratory Failure in Children Under the Age of Two*

In June 2007, we initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from ARF. This Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care with sham air control. Approximately 180 children under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 20 sites throughout the United States, Chile, and Europe. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. The trial is expected to be completed by mid-year 2008.

We are also evaluating the potential development of our proprietary precision-engineered SRT to address respiratory disorders such as cystic fibrosis, ALI, chronic obstructive respiratory disorder (COPD), asthma, and other debilitating respiratory conditions.

## Manufacturing

Our precision-engineered surfactant product candidates, including Surfaxin, must be manufactured in compliance with cGMPs established by the FDA and other international regulatory authorities. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients.

We plan to 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 our manufacturing operations from Laureate (our contract manufacturer at that time) and entered into a transitional services arrangement under which Laureate agreed to provide us with certain limited manufacturing-related support services through December 2006. In July 2006, we completed the transition and terminated the arrangement with Laureate.

Owning the Totowa operation has provided us with direct operational control and, we believe, potentially improved economics for the production of clinical and potential commercial supply of our lead product, Surfaxin, and our SRT pipeline products. This facility is the only facility in which we produce our drug product. We view our acquisition of the Totowa operations as an initial step of our long-term manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

In April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our then contract manufacturer, Laureate, as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. Following a meeting with the FDA on December 21, 2006, and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing.

### Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential worldwide demand for the prevention of RDS in premature infants, the prevention and treatment of BPD and all of our anticipated clinical-scale production requirements for Aerosurf.

We view our acquisition of manufacturing operations in Totowa, NJ as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our Totowa, NJ facility extends through December 2014. In addition to customary lease terms and conditions, 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, in the earlier years, payment to us of significant early termination amounts. Taking into account this early termination option, which may cause us to move out of our Totowa, NJ facility as early as December 2009, our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

## Aerosol Devices and Related Componentry

To manufacture aerosolization systems for our planned clinical trials, we expect to utilize third-party contract manufacturers, suppliers and assemblers. The manufacturing process will require assembly of the key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, the disposable dose delivery packet and patient interface system necessary to administer our aerosolized SRT in patients in the NICU, PICU and ICU. We expect that third-party vendors will manufacture these key device sub-components, and ship them to one central location for assembly and integration into the aerosolization system. Once assembled, critical/product contact components and/or assemblies are packaged and sterilized. Each of the aerosolization systems will be quality-control tested prior to release for use in our clinical trials or, potentially, for commercial use. To complete the combination drug-device product, we plan to manufacture the SRT drug product at our Totowa, NJ facility.

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 in the near term 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.

### **Potential Collaboration Agreements and Strategic Partnerships**

We intend to seek investments of additional capital and potentially enter into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. To assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, in June 2006, we engaged Jefferies & Company, Inc. (Jefferies), a New York-based investment banking firm, under an exclusive arrangement that we terminated in June 2007. We continue, with the assistance of Jefferies and separately, to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

### **CRITICAL ACCOUNTING POLICIES**

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

There have been no changes to our critical accounting policies since December 31, 2006. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2006. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

## RESULTS OF OPERATIONS

The net loss for the three and six months ended June 30, 2007 were \$10.4 million (or \$0.12 per share) and \$18.7 million (or \$0.24 per share), respectively. The net loss for the three and six months ended June 30, 2006 were \$14.7 million (or \$0.24 per share) and \$30.5 million (or \$0.50 per share), respectively.

### Revenue

We did not earn revenue during the three and six months ended June 30, 2007 or 2006.

### Research and Development Expenses

Research and development expenses for the three and six months ended June 30, 2007 were \$6.8 million and \$12.2 million, respectively. Research and development expenses for the three and six months ended June 30, 2006 were \$5.9 million and \$13.5 million, respectively. For a description of expenses and research and development activities, see "Management's Discussion and Analysis - Research and Development." For a description of the clinical programs included in research and development, see "Management's Discussion and Analysis - Plan of Operations."

Research and development expenses for the three and six months ended June 30, 2007 compared to the same periods in 2006 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, in conformance with cGMPs. Expenses associated with manufacturing development activities for the three and six months ended June 30, 2007 were \$2.9 million and \$5.3 million, respectively, as compared to \$2.9 million and \$5.4 million for the three and six months ended June 30, 2006, respectively. Manufacturing development expenses for 2007 primarily consist of (i) costs associated with our manufacturing operations in Totowa, NJ to support the production of clinical and anticipated commercial drug supply for our SRT programs; (ii) continued investment in our quality assurance and analytical chemistry capabilities including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding and upgrading our quality operations to meet production needs for our SRT pipeline in accordance with cGMP; (iii) expenses associated with our comprehensive investigation of the April 2006 Surfaxin process validation stability failure and remediation of our related manufacturing issues.; and (iv) activities to develop additional formulations of our SRT; and
- (ii) Research and development activities, excluding manufacturing development activities, associated with infrastructure development, including clinical trial management, regulatory compliance, data management and biostatistics, and medical and scientific affairs activities as well as direct program expenses to advance our SRT pipeline. Expenses associated with research and development activities for the three and six months ended June 30, 2007 were \$3.9 million and \$6.9 million, respectively, as compared to \$3.0 million and \$8.1 million for the three and six months ended June 30, 2006, respectively. Research and development expenses for 2007 primarily include: (i) costs associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial of Surfaxin for ARF in children up to two years of age; and (iii) development activities related to Aerosurf™. The decrease in the six months ended June 30, 2007 compared to the same period last year primarily reflects cost incurred in 2006 for: (i) clinical activities associated with the Phase 2 clinical trials for BPD in premature infants and ARDS in adults; and (ii) personnel and related costs that were later reduced as a result of staff reductions and reorganization of corporate management that occurred immediately after the April 2006 Surfaxin process validation stability failure.

### General and Administrative Expenses

General and administrative expenses for the three and six months ended June 30, 2007 were \$3.5 million and \$6.2 million, respectively, as compared to \$4.0 million and \$12.7 million for the three and six months ended June 30, 2006, respectively. The decrease is primarily due to costs incurred in 2006 in anticipation of the potential approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. After the April 2006 process validation stability failure, we took immediate steps to lower our costs and suspended pre-launch commercial activities, reduced personnel and reorganized corporate management. General and administrative costs for 2007 primarily include costs associated with executive management, evaluation of various strategic business alternatives, financial and legal management and other administrative costs.

## 2006 Restructuring Charge

Following the April 2006 process validation stability failure, which caused us to revise our expectations concerning the timing of potential FDA approval and pre-launch commercial launch of Surfaxin for the prevention of RDS in premature infants, we reduced our staff levels and reorganized corporate management to lower our cost structure and re-align our operations with changed business priorities. In connection with the workforce reduction, the employment of three senior executives was terminated. The reduction in workforce totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on our commercial infrastructure. All affected employees were eligible for certain severance payments and continuation of benefits. Additionally, a number of pre-launch commercial programs were discontinued and related costs will no longer be incurred. Such commercial program expenses totaled approximately \$5.0 million for the fourth quarter of 2005 and first quarter of 2006.

We incurred a restructuring charge of \$4.8 million in the second quarter of 2006 associated with the staff reductions and close-out of certain pre-launch commercial programs, which was accounted for in accordance with Statement No. 146 "Accounting for Costs Associated with Exit or Disposal Activities" and is identified separately on our Statement of Operations as a Restructuring Charge. This charge included \$2.5 million of severance and benefits related to staff reductions and \$2.3 million for the termination of certain pre-launch commercial programs. As of June 30, 2007, the remaining balance of the unpaid restructuring charge totals \$0.6 million, of which \$0.5 million was included in accounts payable and accrued expenses and \$0.1 million was classified as a long-term liability.

## Other Income and (Expense)

Other income and (expense) for the three and six months ended June 30, 2007 were (\$0.1) million and (\$0.3) million, respectively. Other income and (expense) for the three and six months ended June 30, 2006 were \$45,000 and \$0.5 million, respectively.

Interest and other income for the three and six months ended June 30, 2007 was \$0.6 million and \$0.9 million, respectively, as compared to \$0.4 million and \$1.2 million for the three and six months ended June 30, 2006, respectively. The increase for the three months ended June 30, 2007 as compared to the same period last year is primarily due to an increase in our average outstanding cash balance and a general increase in earned market interest rates. The decrease for the six months ended June 30, 2007 as compared to the same period last year is primarily due to proceeds of \$0.3 million in the first quarter of 2006 from the sale of our Commonwealth of Pennsylvania research and development tax credits.

Interest, amortization and other expenses for the three and six months ended June 30, 2007 was \$0.7 million and \$1.1 million, respectively, as compared to \$0.3 million and \$0.6 million for the three and six month ending June 30, 2006, respectively. The increase is primarily due to: (i) interest expense related to the amortization of deferred financing costs associated with warrants issued to PharmaBio in October 2006 in consideration for renegotiating the terms on the existing \$8.5 million loan and (ii) a prepayment penalty of \$0.2 million incurred in the second quarter of 2007 associated with the prepayment of our outstanding indebtedness with GECC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

We have incurred substantial losses since inception and expect to continue to make significant investments for continued product research, development, manufacturing and commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities and the use of debt and capital lease facilities.

We are subject to risks customarily associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

We plan to fund our research, development, manufacturing and potential commercialization activities through:

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

Our capital requirements will depend on many factors, including the success of the product development and commercialization plan. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability. There is no assurance that we will be able to obtain additional capital when needed with acceptable terms, if at all.

To assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, in 2006, we engaged Jefferies under an exclusive arrangement that we terminated in June 2007. In November 2006, we raised \$10 million in a private placement transaction and, in April 2007, we raised \$30.2 million (\$28.1 million net) in a registered direct offering. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

We have a CEFF that allows us to raise capital, subject to certain conditions, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions (discussed at “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility”, below), including a limitation on the total number of shares of common stock that we may issue under the CEFF (not more than approximately 7.1 million shares as of June 30, 2007). We anticipate using the CEFF, when available, to support working capital needs in 2007.

### **Cash, Cash Equivalents and Marketable Securities**

As of June 30, 2007, we had cash, cash equivalents, restricted cash and marketable securities of \$40.8 million, as compared to \$27.0 million as of December 31, 2006. The increase is primarily due to: (i) a registered direct offering in April to institutional investors resulting in gross proceeds of \$30.2 million (\$28.1 million net) from the issuance of 14,050,000 shares of common stock at \$2.15 per share and (ii) proceeds of \$2.0 million from a financing pursuant to the CEFF; offset by \$16.6 million used in operating activities, purchases of capital expenditures and principal payments on capital lease arrangements.

### **Committed Equity Financing Facility**

In April 2006, we entered into a new CEFF with Kingsbridge, 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, which was with Kingsbridge, entered in July 2004 (2004 CEFF) and under which up to \$47.6 million remained 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.



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

The purchase price of shares sold to Kingsbridge under the CEFF is 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 initiation of a “draw down” under the CEFF. The discount on each of these eight trading days is determined as follows:

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

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

If on any trading day during the eight trading day pricing period for a draw down, the VWAP 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, no shares will be issued with respect to that trading day and the total amount of the draw down will be reduced by one-eighth of the draw down amount we had initially specified.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of our outstanding shares of our common stock at the time of the draw down or \$10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. In addition, Kingsbridge may terminate the CEFF under certain circumstances, including if a material adverse effect relating to our business continues for 10 trading days after notice of the material adverse effect.

In 2006, in connection with the 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 is exercisable for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.8 million.

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

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

In November 2006, we completed a financing pursuant to the CEFF resulting in proceeds of \$3 million from the issuance of 1,371,516 shares of our common stock at an average price per share, after the applicable discount, of approximately \$2.19.

In February 2007, we completed a financing pursuant to the CEFF resulting in proceeds of \$2 million from the issuance of 942,949 shares of our common stock at an average price per share, after the applicable discount, of \$2.12.

As of June 30, 2007, there were approximately 7.1 million shares available for issuance under the CEFF (up to a maximum of \$40.5 million in gross proceeds) for future financings.

In 2004, 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, is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds, if exercised, of approximately \$4.5 million. As of December 31, 2006, the Class B Investor Warrant had not been exercised.

## 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 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 million. In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors resulting in gross proceeds of \$30.2 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately \$49.8 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

#### *Loan with PharmaBio*

PharmaBio, the strategic investment group of Quintiles, extended to us a secured, revolving credit facility of \$8.5 to \$10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. Previously, interest was payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. In 2004, we renegotiated the loan and the maturity date was extended from December 10, 2004 to December 31, 2006. The interest rate remained unchanged. In October 2006, we restructured the existing \$8.5 million loan with PharmaBio and, as a result, the maturity date of the loan has been further extended from December 31, 2006 to April 30, 2010.

Since October 1, 2006, interest on the loan has accrued at the prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, will now be payable on April 30, 2010, the maturity date of the loan. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium.

In connection with the restructuring, in October 2006, we and PharmaBio amended and restated the existing loan documents. In addition, our obligations to PharmaBio under the loan documents are now secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the Security Agreement (the PharmaBio Collateral).

Also in October 2006, in consideration of PharmaBio's agreement to restructure the loan, we entered into a Warrant Agreement with PharmaBio, pursuant to which PharmaBio has the right to purchase 1.5 million shares of our common stock at an exercise price equal to \$3.5813 per share. The warrants have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we filed a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants.

As of June 30, 2007, the outstanding balance under the loan was \$9.3 million (\$8.5 million of pre-restructured principal and \$0.8 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

#### *Capital Lease Financing Arrangements with Merrill Lynch Capital*

On May 21, 2007, we and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. (Merrill Lynch), entered into a Credit and Security Agreement (Loan Agreement), pursuant to which Merrill Lynch is providing us \$12.5 million credit facility (Facility) to fund our capital programs. Under the Facility, \$9 million was immediately available with up to an additional \$3.5 million becoming available, at a rate of \$1 million for each \$10 million raised by us through business development partnerships, stock offerings and other similar financings. Approximately \$4 million of the Facility has been drawn to fund the prepayment (GECC Pay Down) of all our outstanding indebtedness to General Electric Capital Corporation (GECC) under the Master Security Agreement with GECC dated December 20, 2002, as amended (GECC Agreement). The right to draw funds under the Facility will expire on May 30, 2008, subject to a best efforts undertaking by Merrill Lynch to extend the draw down period beyond the expiration date for an additional six months. The minimum advance under the Facility is \$100,000. Interest on each advance will accrue at a fixed rate per annum equal to LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances will be payable in equal installments on the first business day of each month. We may prepay advances, in whole or in part, at any time, subject to a prepayment penalty, which, depending on the period of time elapsed from the closing of the Facility, will range from 4% to 1%.

We may use the Facility to finance (a) new property and equipment and (b) up to approximately \$1.7 million "Other Equipment" and related costs, which may include leasehold improvements, intangible property such as software and software licenses, specialty equipment, a pre-payment penalty which was paid to GECC and "soft costs" related to financed property and equipment (including, without limitation, taxes, shipping, installation and other similar costs). Advances to finance the acquisition of new property and equipment will be amortized over a period of 36 months. The advance related to the GECC Pay Down will be amortized over a period of 27 months and Other Equipment and related costs will be amortized over a period of 24 months.

Our obligations to Merrill Lynch are secured by a security interest in (a) the financed property and equipment, including the property and equipment securing GECC at the time of the GECC Pay Down, and (b) all of our intellectual property, subject to limited exceptions set forth in the Loan Agreement (Supplemental Collateral). The Supplemental Collateral will be released on the earlier to occur of (i) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of respiratory distress syndrome in premature infants, or (ii) the date on which we shall have maintained over a continuous twelve-month period ending on or after March 31, 2008, measured at the end of each calendar quarter, a minimum cash balance equal to our projected cash requirements for the following twelve-month period. In addition, Merrill Lynch agreed to subordinate its security interest in the Supplemental Collateral to the security interest in the same collateral that we previously granted to PharmaBio.

Previously, our capital lease financing arrangements had been primarily with the Life Science and Technology Finance Division of GECC pursuant to the Master Security Agreement. Under the Master Security Agreement, we purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through capital leases. The loans were secured by the related assets. Laboratory and manufacturing equipment were financed over 48 months and all other equipment were financed over 36 months. Interest rates varied in accordance with changes in the three and four year treasury rates.

As of June 30, 2007, \$4.2 million was outstanding under the Facility (\$1.7 million classified as current liabilities and \$2.5 million as long-term liabilities) and \$4.8 million remained available for use, subject to the conditions of the Facility.

### **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. In April 2007, the lease, which originally expired in February 2010 with total aggregate payments of \$4.6 million, was extended an additional three years through February 2013 with additional payments of \$3.0 million over the extension period.

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.

In August 2006, we reduced our leased office and analytical laboratory space in Doylestown, Pennsylvania from approximately 11,000 square feet to approximately 5,600 square feet and extended the lease that expires in August 2007 and is thereafter 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.

If we are successful in commercializing our SRT portfolio, we expect that our needs for additional leased space will increase.

### **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, 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 equipment financing facility with Merrill Lynch, the use of which are subject to certain conditions, we have no contractual arrangements under which we may obtain additional financing.

To assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, in 2006, we engaged Jefferies under an exclusive arrangement that we terminated in June 2007. In November 2006, we raised \$10 million in a private placement transaction and, in April 2007, we raised \$30.2 million (\$28.1 million net) in a registered direct offering. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

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

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### *(a) Evaluation of disclosure controls and procedures*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our 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 our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Officer and our 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, our Chief Executive Officer and our Chief Financial Officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us 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**

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased our publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various of our public statements. The amended complaint had been filed on November 30, 2006 against us, our Chief Executive Officer, Robert J. Capetola, and our former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs 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 April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania. Plaintiffs filed an opening brief on July 2, 2007 and defendants filed their opening brief on August 6, 2007. Plaintiffs must file their reply brief on August 20, 2007.

On May 1, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the consolidated shareholder derivative complaint that was filed on December 29, 2006 under the caption "In re: Discovery Laboratories Derivative Litigation." The complaint named as defendants our Chief Executive Officer, Robert J. Capetola, four of our outside directors - Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, and Christopher J. Schaber, our former Chief Operating Officer, and sought an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. Although they were granted leave to file a second amended complaint by May 15, 2007, plaintiffs did not re-file. As the period during which an appeal may be filed has expired, this matter is concluded.

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

We have from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination in 2006 of certain pre-launch commercial programs following our process validation stability failure. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, we believe the pending matters are unlikely to have a material adverse effect on our financial condition or results of operations. However, there can be no assurance that we will be successful in any proceeding to which we are or may be a party.

#### **ITEM 1A. RISK FACTORS**

In addition to the risks, uncertainties and other factors set forth herein, see the "Risk Factors" section contained in our most recent Annual Report on Form 10-K.

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

During the three and six months ended June 30, 2007, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options. There were no stock repurchases during the three and six months ended June 30, 2007.

#### **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 21, 2007 the following matters were voted on by the stockholders: (i) the election of six directors; (ii) the approval of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2007; and (iii) consideration and approval of Discovery Labs 2007 Long-Term Incentive Plan, with 8.5 million shares of our common stock, par value \$.001 per share, available for issuance under such plan. The results of such shareholder votes are as follows:

(i) Election of Directors

|                             | For        | Withheld  |
|-----------------------------|------------|-----------|
| W. Thomas Amick             | 67,587,117 | 8,569,843 |
| Robert J. Capetola, Ph.D.   | 70,813,504 | 5,343,456 |
| Antonio Esteve, Ph.D.       | 66,267,187 | 9,889,773 |
| Max Link, Ph.D.             | 67,252,163 | 8,904,797 |
| Herbert H. McDade, Jr.      | 71,314,702 | 4,842,258 |
| Marvin E. Rosenthale, Ph.D. | 67,506,812 | 8,650,148 |

(ii) Approval of Ernst & Young LLP as our Independent Registered Public Accounting Firm

| <u>For</u> | <u>Against</u> | <u>Abstain</u> |
|------------|----------------|----------------|
| 75,813,959 | 268,314        | 74,687         |

(iii) Approval of Discovery Labs 2007 Long-Term Incentive Plan

| <u>For</u> | <u>Against</u> | <u>Abstain</u> | <u>Non-Vote</u> |
|------------|----------------|----------------|-----------------|
| 24,804,201 | 11,800,932     | 136,377        | 39,415,450      |

**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, 2007

By: /s/ Robert J. Capetola

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

Date: August 9, 2007

By: /s/ John G. Cooper

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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 on Form 10-Q.

| <u>Exhibit No.</u> | <u>Description</u>  | <u>Method of Filing</u>  |
|--------------------|---|--|
| 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                | 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.   |
| 3.3                | 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.   |
| 3.4                | 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.        |
| 3.5                | 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.        |
| 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 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. |
| 4.3                | 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.  |
| 4.4                | 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.  |
| 4.5                | 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.  |

|      |   |   |
|------|---|---|
| 4.6  | 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.    |
| 4.7  | 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.     |
| 4.8  | Registration Rights Agreement, dated as of April 17, 2006, 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 April 21, 2006.   |
| 4.9  | Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. ("PharmaBio")   | Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.  |
| 4.10 | Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio   | Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.  |
| 4.11 | Warrant Agreement, dated November 22, 2006  | Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006. |
| 10.1 | Credit and Security Agreement, dated as of May 21, 2007, by and between Discovery Laboratories, Inc. and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services, Inc. | Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 24, 2007.     |
| 10.2 | Discovery Laboratories, Inc. 2007 Long Term Incentive Plan  | Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.     |
| 10.3 | Form of Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan Stock Option Agreement   | Filed herewith  |
| 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.   |

[bracketed language to be included based on a determination by the Committee at the time of the grant.]

**DISCOVERY LABORATORIES, INC.  
2007 LONG-TERM INCENTIVE PLAN  
STOCK OPTION AGREEMENT**

**RECITALS**

A. The Board has adopted the Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan (the "Plan") for the purpose of encouraging selected Employees, Directors and Consultants of the Company and its Subsidiaries to acquire a proprietary interest in the growth and performance of the Company, to generate an increased incentive to contribute to the Company's future success and prosperity, thus enhancing the value of the Company for the benefit of its shareholders, and to enhance the ability of the Company and its Subsidiaries to attract and retain exceptionally qualified individuals upon whom, in large measure, the sustained progress, growth and profitability of the Company depend.

The administrator of the Plan is a committee of the Board of Directors or its delegate (the "Committee"), as contemplated by Section 3 of the Plan.

B. Participant is to render valuable Services to the Company (or Subsidiary), and this Award Agreement is executed pursuant to, and is intended to carry out the purposes of, the Plan in connection with the Company's grant of an option to Participant.

C. All capitalized terms in this Stock Option Agreement ("Award Agreement") shall have the meaning assigned to them in the attached Appendix or, if not otherwise defined in the Appendix, in the Plan.

**NOW, THEREFORE**, it is hereby agreed as follows:

1. **Award of Option.** The Company hereby grants to Participant, as of the Award Date, an option to purchase up to the number of Option Shares specified in the Notice of Award. The Option Shares shall be purchasable from time to time as specified in Paragraph 4 during the option term specified in Paragraph 2 at the Exercise Price set forth on the Notice of Award.

2. **Option Term.** This option shall have the term set forth on the Notice of Award, up to a maximum term of ten (10) years measured from the Award Date and shall expire at the close of business on the Expiration Date set forth on the Notice of Award, unless sooner terminated in accordance with Paragraph 5 or 6.

3. **Limited Transferability.** The option granted under this Award Agreement shall not be assignable, alienable, saleable, or transferable by Participant other than by will or by the laws of descent and distribution; provided, however, that, if a procedure shall be adopted by the Committee at any time, Participant may designate a beneficiary or beneficiaries to exercise the rights of Participant with respect to this option upon Participant's death. The option granted under this Award Agreement shall be exercisable during Participant's lifetime only by Participant or, if permissible under applicable law, by Participant's guardian or legal representative. This option may not be pledged, alienated, attached, or otherwise encumbered, and any purported pledge, alienation, attachment, or encumbrance thereof shall be void and unenforceable against the Company or any affiliate of the Company. Notwithstanding the foregoing, if this option is designated a Non-Qualified Stock Option in the Notice of Award, then this option may, in connection with Participant's estate plan, be assigned, in whole or in part, during Participant's lifetime to one or more members of Participant's immediate family or to a trust established for the exclusive benefit of one or more such family members. The assigned portion shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment and shall be set forth in such documents issued to the assignee as the Committee may deem appropriate.

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4. **Dates of Exercise.** This option shall vest and become exercisable for the Option Shares in one or more installments as specified in the Notice of Award. As the option becomes exercisable for such installments, those installments shall accumulate, and the option shall remain exercisable for the accumulated installments until the Expiration Date or sooner termination of the option term under Paragraph 5 or 6.

5. **Termination of Service.** The option term specified in Paragraph 2 shall terminate (and this option shall expire and cease to be exercisable) prior to the Expiration Date should any of the following provisions become applicable:

(a) If Participant's Service is terminated for any reason other than death, Disability or for Cause, then Participant shall have the right to exercise, in whole or in part, that portion of this option that was vested and exercisable on the date of termination of Service until the earlier of (i) three (3) months after termination of Service or (ii) the Expiration Date; and, to the extent that any portion of this option was not exercisable on the date of termination of Service, it will immediately terminate.

(b) If Participant's Service is terminated on account of death (or if a Participant dies within ninety days following termination of employment due to Disability), then Participant's Beneficiary shall have the right to exercise, in whole or in part, that portion of this option that was vested and exercisable on the date of date until the earlier of (A) the first anniversary of the date of Participant's death or (B) the Expiration Date; and, to the extent that any portion of this option was not exercisable on the date of termination of Service, it will immediately terminate.

(c) If Participant's Service is terminated on account of Disability, then Participant or Participant's Beneficiary shall have the right to exercise, in whole or in part, that portion of this option that was vested and exercisable on the date of Disability until the earlier of (i) ninety (90) days after termination of Service or (ii) the Expiration Date; and, to the extent that any portion of this option was not exercisable on the date of termination of Service, it will immediately terminate.

(d) If Participant's Service is terminated for Cause or if Participant shall breach any post-Service duties to the Company or any post-Service covenants or agreements, including any confidentiality or non-competition and non-solicitation agreement, any unexercised portion of this option shall terminate immediately. Solely for the purposes of this Award Agreement, notwithstanding any notice period or cure period provided in any employment or other applicable agreement, if Participant is terminated for Cause, the date of termination shall be deemed to be the date as of which the Company issues a notice of termination to Participant (subject to any right that the Participant may have to cure). The right to exercise any vested and unexercised portion of this option shall be suspended during any such notice or cure period. Should the Company revoke any notice of termination based on Participant's satisfactory cure under an employment or other applicable agreement, the Committee may reinstate the right to exercise this option under the original terms of this Award Agreement.

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[(e) to be included in Award Agreements for non-employee directors only]

(e) If Participant's Service is as a member of the Board ("Board Service"), in lieu of clauses (a) through (c) of this Paragraph 6, the following provisions shall apply:

(i) The Participant (or, in the event of the Participant's death, the personal representative of the Participant's estate or the person or persons to whom this option is transferred pursuant to the Participant's will or in accordance with the laws of descent and distribution) may exercise that portion of this option that was vested and exercisable until the earlier of (A) twelve (12) months following the date of such cessation of Board Service, or (B) the Expiration Date.

(ii) During the post-Board Service period, this option may not be exercised in the aggregate for more than the number of vested Shares for which the Option was exercisable at the time of the Participant's cessation of Board Service.

(iii) Should the Participant cease to serve as a Board member by reason of death or Disability, then vesting under this option shall accelerate and this option shall become exercisable with respect to the total number of Option Shares subject to this option and may be exercised for any or all of those Option Shares until the earlier of (A) twelve (12) months following cessation of Board Service or (B) the Expiration Date.

(iv) This option shall, immediately upon the Participant's cessation of Board Service for any reason other than death or Disability, terminate and cease to be outstanding to the extent the Option is not otherwise at that time exercisable for vested Shares.

6. **Special Acceleration of Option.** Except as otherwise expressly provided in a Participant's employment or other applicable agreement, which shall supersede the provisions of this Paragraph 6 solely to the extent that the rights and privileges under such agreement, as determined by the Committee, in its discretion, are not reasonably likely to significantly diminish the rights and benefits that would otherwise be provided under this paragraph 6:

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(a) In the event of a Corporate Transaction, vesting under this option shall automatically accelerate so that, immediately prior to the effective date of the Corporate Transaction, this option shall become exercisable with respect to the total number of Option Shares at the time subject to this option and may be exercised for any or all of those Option Shares. [However, vesting under this option shall not so accelerate if and to the extent: (i) this option is, in connection with the Corporate Transaction, either to be assumed by the successor corporation (or parent thereof) or to be replaced with a comparable option to purchase shares of the capital stock of the successor corporation (or parent thereof), or (ii) this option is to be replaced with a cash incentive program of the successor corporation which preserves the spread existing on any unvested Option Shares at the time of the Corporate Transaction (the excess of the Fair Market Value of those Option Shares over the aggregate Exercise Price payable for such Option Shares) and provides for subsequent pay-out in accordance with the same option vesting schedule set forth in the Notice of Award. The determination of comparability under clause (i) above shall be made by the Committee, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, the Committee shall have the discretion, exercisable at any time during the term of this Award Agreement, to provide for the automatic acceleration of all or a portion of this option upon the occurrence of a Corporate Transaction, whether or not this option is to be assumed or replaced in the Corporate Transaction.]

(b) In the event Participant's Service is terminated by reason of an Involuntary Termination within eighteen (18) months following the effective date of any Corporate Transaction in which this option is assumed or replaced and does not otherwise accelerate, vesting under this option shall accelerate automatically and this option shall remain exercisable until the earlier of (i) the Expiration Date or (ii) the expiration of a one (1)-year period measured from the effective date of the Involuntary Termination.

(c) If this option is assumed in connection with a Corporate Transaction, then this option shall be appropriately adjusted, immediately after such Corporate Transaction, to apply to the number and class of securities which would have been issuable to Participant in consummation of such Corporate Transaction had the option been exercised immediately prior to such Corporate Transaction, and appropriate adjustments shall also be made to the Exercise Price per Share, provided the aggregate Exercise Price shall remain the same.

(d) Upon the occurrence of [ a Change in Control or ] [the termination of Participant's Service by reason of an Involuntary Termination within eighteen (18) months following the effective date of a Change in Control], vesting under this option shall accelerate automatically and this option shall become exercisable with respect to the total number of Shares at the time subject to this option and shall remain exercisable until the earlier of (i) the Expiration Date or (ii) if applicable, the expiration of the a (1)-year period measured from the effective date of the Involuntary Termination.

(e) This Award Agreement shall not in any way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

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7. **Repurchase Right.** if at any time Participant's Service is terminated for Cause or if Participant shall breach any post-termination covenants set forth in any written agreement between Participant and the Company, the Company may, in its discretion, for a period of one year after the termination for Cause or the actual discovery by the Company of the breach, as the case may be, and upon 10 (ten) days' notice to Participant, (i) repurchase all or any portion of any Option Shares acquired by Participant upon Participant's exercise of this option, and/or (ii) require Participant to repay to the Company the amount of any profits realized by Participant upon the sale or other disposition during the preceding three years of any Option Shares acquired by Participant upon Participant's exercise of this option. The purchase price for any Shares repurchased by the Company pursuant to clause (i) of this Section 7 shall be the lesser of the price paid by Participant to acquire such Shares and the Fair Market Value thereof on the date of such purchase by the Company.

8. **Adjustment in Option Shares.** Should any change be made to the Common Stock by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Common Stock as a class without the Company's receipt of consideration, appropriate adjustments shall be made to (i) the total number and/or class of securities subject to this option and (ii) the Exercise Price in order to reflect such change and thereby preclude a dilution or enlargement of benefits hereunder.

9. **Stockholder Rights.** The holder of this option shall not have any stockholder rights with respect to the Option Shares until such person shall have exercised the option, paid the Exercise Price and become a holder of record of the purchased Shares.

10. **Manner of Exercising Option.**

(a) In order to exercise this option with respect to all or any part of the Option Shares for which this option is at the time exercisable, Participant (or any other person or persons exercising the option) must take the following actions:

(i) Execute and deliver to the Company a Notice of Exercise for the Option Shares for which the option is exercised.

(ii) Pay the aggregate Exercise Price for the purchased Shares in one or more of the following forms:

(A) cash or check made payable to the Company;

(B) Shares held by Participant (or any other person or persons exercising the option) for the requisite period necessary to avoid a charge to the Company's earnings for financial reporting purposes and valued at Fair Market Value on the Exercise Date; or

(C) provided that no restrictions against trading in the Shares are then in effect, as contemplated by Paragraph 11, through a special sale and remittance procedure pursuant to which Participant (or any other person or persons exercising the option) shall concurrently provide irrevocable instructions (I) to a Company-approved brokerage firm to effect the immediate sale of the purchased Shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate Exercise Price payable for the purchased Shares plus all applicable income and employment taxes required to be withheld by the Company by reason of such exercise and (II) to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale.

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Except to the extent the sale and remittance procedure is utilized in connection with the option exercise, payment of the Exercise Price must accompany the Notice of Exercise delivered to the Company in connection with the option exercise.

(iii) Furnish to the Company appropriate documentation that the person or persons exercising the option (if other than Participant) have the right to exercise this option.

(iv) Make appropriate arrangements with the Company (or Parent or Subsidiary employing or retaining Participant) for the satisfaction of all income and employment tax withholding requirements applicable to the option exercise.

(b) As soon as practical after the Exercise Date, the Company shall issue to or on behalf of Participant (or any other person or persons exercising this option) a certificate for the purchased Option Shares, with the appropriate legends affixed thereto.

(c) In no event may this option be exercised for any fractional shares.

11. **Compliance with Laws and Regulations.**

(a) The exercise of this option and the issuance of the Option Shares upon such exercise shall be subject to compliance by the Company and Participant with all applicable requirements of law relating thereto and with all applicable regulations of any stock exchange (or the Nasdaq National Market, if applicable) on which the Common Stock may be listed for trading at the time of such exercise and issuance.

(b) The inability of the Company to obtain approval from any regulatory body having authority deemed by the Company to be necessary to the lawful issuance and sale of any Common Stock pursuant to this option shall relieve the Company of any liability with respect to the non-issuance or sale of the Common Stock as to which such approval shall not have been obtained. The Company, however, shall use its best efforts to obtain all such approvals.

12. **Successors and Assigns.** Except to the extent otherwise provided in Paragraphs 3 and 6, the provisions of this Award Agreement shall inure to the benefit of, and be binding upon, the Company and its successors and assigns and Participant and Participant's assigns and Beneficiaries.

13. **Notices.** Any notice required to be given or delivered to the Company under the terms of this Award Agreement shall be in writing and addressed to the Company at its principal corporate offices. Any notice required to be given or delivered to Participant shall be in writing and addressed to Participant at the address indicated below Participant's signature line on the Notice of Award. All notices shall be deemed effective upon personal delivery or upon deposit in the U.S. mail, postage prepaid and properly addressed to the party to be notified.

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14. **Construction.** This Award Agreement and the option evidenced hereby are made and granted pursuant to the Plan and are in all respects limited by and subject to the terms of the Plan. All decisions of the Committee with respect to any question or issue arising under the Plan or this Award Agreement shall be conclusive and binding on all persons having an interest in this option.

15. **Governing Law.** The interpretation, performance and enforcement of this Award Agreement shall be governed by the laws of the State of Delaware without resort to that State's conflict-of-laws rules.

16. **Excess Shares.** If the Option Shares covered by this Award Agreement exceed, as of the Award Date, the number of Shares which may without stockholder approval be issued under the Plan, then this option shall be void with respect to those excess Shares, unless stockholder approval of an amendment sufficiently increasing the number of Shares issuable under the Plan is obtained in accordance with the provisions of the Plan.

17. **Additional Terms Applicable to an Incentive Stock Option.** The terms of any Incentive Stock Option granted under the Plan shall be designed to comply in all respects with the provisions of Sections 422 of the Code, or any successor provision thereto, and any regulations promulgated thereunder. Notwithstanding anything in this Section 17 to the contrary, Options designated as Incentive Stock Options shall not be eligible for treatment under the Code as Incentive Stock Options (and will be deemed to be Non-Qualified Stock Options) to the extent that either (1) the aggregate Fair Market Value of Shares (determined as of the time of grant) with respect to which such Options are exercisable for the first time by Participant during any calendar year (under all plans of the Company and any Subsidiary) exceeds \$100,000, taking Options into account in the order in which they were granted, or (2) such Options otherwise remain exercisable but are not exercised within three (3) months of termination of employment (or such other period of time provided in Section 422 of the Code).

18. **Leave of Absence.** The following provisions shall apply upon Participant's commencement of an authorized leave of absence:

(a) The exercise schedule in effect under the Notice of Award shall be frozen as of the first day of the authorized leave, and this option shall not become exercisable for any additional installments of the Option Shares during the period Participant remains on such leave.

(b) Should Participant resume active Employee status within sixty (60) days after the start date of the authorized leave, Participant shall, for purposes of the exercise schedule set forth in the Notice of Award, receive Service credit for the entire period of such leave. If Participant does not resume active Employee status within such sixty (60)-day period, then no Service credit shall be given for the period of such leave.

(c) If this option is designated as an Incentive Stock Option in the Notice of Award, then the following additional provision shall apply:

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(i) If the leave of absence continues for more than ninety (90) days, then this option shall automatically convert to a Non-Qualified Stock Option at the end of the three (3)-month period measured from the ninety-first (91st) day of such leave, unless Participant's reemployment rights are guaranteed by statute or by written agreement. Following any such conversion of this option, all subsequent exercises of this option, whether effected before or after Participant's return to active Employee status, shall result in an immediate taxable event, and the Company shall be required to collect from Participant the income and employment withholding taxes applicable to such exercise.

(ii) In no event shall this option become exercisable for any additional Option Shares or otherwise remain outstanding if Participant does not resume Employee status prior to the Expiration Date of the option term.

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**EXHIBIT I  
NOTICE OF EXERCISE**

I hereby notify Discovery Laboratories, Inc. (the "Company") that I elect to purchase \_\_\_\_\_ shares of the Company's Common Stock (the "Purchased Shares") at the option exercise price of \$\_\_\_\_\_ per share (the "Exercise Price") pursuant to that certain option (the "Option") granted to me under the Company's 2007 Stock Incentive Plan on \_\_\_\_\_, \_\_\_\_\_.

Concurrently with the delivery of this Exercise Notice to the Company, I shall hereby pay to the Company the Exercise Price for the Purchased Shares in accordance with the provisions of my agreement with the Company (or other documents) evidencing the Option and shall deliver whatever additional documents may be required by such agreement as a condition for exercise. Alternatively, if I am eligible I may utilize the special broker-dealer sale and remittance procedure specified in my agreement to effect payment of the Exercise Price.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Print name in exact manner  
it is to appear on the  
stock certificate:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Address to which certificate  
is to be sent, if different  
from address above:

\_\_\_\_\_  
\_\_\_\_\_

Social Security Number:

\_\_\_\_\_

Employee Number:

\_\_\_\_\_

\_\_\_\_\_

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## APPENDIX

The following definitions shall be in effect under the Award Agreement:

**Award Agreement** shall mean this Stock Option Agreement.

**Award Date** shall mean the date of grant of the option as specified in the Notice of Award.

**Beneficiary** shall mean, in the event the Committee implements a beneficiary designation procedure, the person designated by Participant, pursuant to such procedure, to succeed to such person's rights under any outstanding awards held by Participant at the time of death. In the absence of such procedure or designation, the Beneficiary shall be Participant's personal representative or the person or persons to whom the Award is transferred by will or the laws of descent and distribution.

**Board** shall mean the Company's Board of Directors.

**Cause**, with respect to any Employee or Consultant of the Company or a Subsidiary, shall have the meaning set forth in such person's employment, consulting or other applicable agreement, or, in the absence of any such agreement or if such term is not defined in any such agreement, shall mean any one or more of the following, as determined by the Committee:

- (i) willful misconduct or gross negligence in the performance of such person's duties;
- (ii) willful and continued failure or refusal to perform satisfactorily any duties reasonably requested in the course of such person's employment by, or service to, the Company (other than a failure resulting from such person's disability); or
- (iii) fraudulent, dishonest or other improper conduct engaged in by such person that causes, or has the potential to cause, harm to the Company or any of its Subsidiaries, or its or their business or reputation, including, without limitation, such person's violation of any policies of the Company applicable to the such person, such person's violation of laws, rules or regulations applicable to such person, criminal activity, habitual drunkenness or use of illegal drugs.

**Change in Control** shall have the meaning, if any, set forth in a Participant's employment, consulting or other applicable agreement, or, if such term is not defined in any such agreement, shall mean the occurrence of any of the following events:

- (i) the acquisition, directly or indirectly by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the Securities Exchange Act of 1934, as amended) of securities possessing more than thirty-five percent (35%) of the total combined voting power of the Company's outstanding securities;
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- (ii) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board ceases to consist of Incumbent Members, which term means members of the Board on the first day of such period and any person becoming a member of the Board subsequent to such date whose election or nomination for election was approved by two-thirds of the members of the Board who then comprised the Incumbent Directors; or
- (iii) the Company combines with another company and is the surviving corporation but, immediately after the combination, the shareholders of the Company immediately prior to the combination hold, directly or indirectly, by reason of their being stockholders of the Company, fifty percent (50%) or less of the voting stock of the combined entity.

**Code** shall mean the Internal Revenue Code of 1986, as amended from time to time.

**Committee** shall mean a committee of the Board, acting in accordance with the provisions of Section 3 of the Plan, designated by the Board to administer the Plan.

**Common Stock** shall mean the Company's common stock.

**Consultant** shall mean any person, including a Director, who is not an Employee and who is engaged by the Company (or a Subsidiary) to render services to or for the benefit of the Company and is compensated for such services.

**Corporate Transaction** shall mean a liquidation of the Company, a sale of all or substantially all of the Company's assets, or a merger, consolidation or similar transaction in which the Company is not the surviving entity or survives as a wholly-owned or majority-owned subsidiary of another entity.

**Director** shall mean a member of the Board.

**Disability** shall have the meaning set forth in Participant's employment agreement or other similar agreement with the Company; provided, that, if such term is not defined in any such agreement or if Participant is not a party to any such agreement, then "Disability" shall mean a permanent and total disability, within the meaning of Section 22(e)(3) of the Code.

**Employee** shall mean any person treated as an employee (including officers and directors) in the records of the Company or any Subsidiary and who is subject to the control and direction of the Company or any Subsidiary with regard to both the work to be performed and the manner and method of performance.

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**Exercise Date** shall mean the date on which the option shall have been exercised in accordance with Paragraph 10 of this Award Agreement.

**Exercise Date** shall mean the purchase price payable for Option Shares under this option, as specified in the Notice of Award.

**Expiration Date** shall mean the date on which the option expires as specified in the Notice of Award.

**Fair Market Value** per share of Common Stock on any relevant date shall be determined in accordance with the following provisions:

- (i) if the Shares are listed or admitted for trading on any United States national securities exchange, or if actual transactions are otherwise reported on a consolidated transaction reporting system, the last reported sale price of a Share on such exchange or reporting system, as reported in any newspaper of general circulation, or
- (ii) if clause (i) is not applicable, the mean of the high bid and low asked quotations for a Share as reported by the National Quotation Bureau, Incorporated if at least two securities dealers have inserted both bid and asked quotations for the Shares on at least five of the 10 preceding trading days; or
- (iii) if the information set forth in clauses (i) through (ii) above is unavailable or inapplicable to the Company (e.g., if the Shares are not then publicly traded or quoted), then the "Fair Market Value" of a Share shall be the fair market value (i.e., the price at which a willing seller would sell a Share to a willing buyer when neither is acting under compulsion and when both have reasonable knowledge of all relevant facts) of a Share on such date as the Committee in its sole and absolute discretion shall determine in a fair and uniform manner.

**Incentive Stock Option** shall mean an option that is intended to meet the requirements of Section 422 of the Code

**Involuntary Termination** shall mean the termination of the Service of any individual which occurs by reason of:

- (i) such individual's involuntary dismissal or discharge by the Company for reasons other than Cause, or
  - (ii) such individual's voluntary resignation following (A) a change in his or her position with the Company (or Subsidiary employing such individual) which materially reduces such individual's duties and responsibilities or the level of management to which such individual reports, (B) a reduction in such individual's level of compensation (including base salary, fringe benefits and target bonus under any corporate performance-based bonus or incentive programs) by more than fifteen percent (15%) or (C) a relocation of such individual's place of employment by more than fifty (50) miles, provided and only if such change, reduction or relocation is effected by the Company without such individual's consent.
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**Non-Employee Director** shall mean a Director who is not also an Employee.

**Non-Qualified Stock Option** shall mean an option granted under this Award Agreement that is not intended to be an Incentive Stock Option.

**Notice of Award** shall mean the Notice of Award of Stock Option accompanying the Award Agreement, pursuant to which Participant has been informed of the basic terms of the option evidenced hereby.

**Notice of Exercise** shall mean the notice of exercise in the form attached hereto as Exhibit I.

**Option Shares** shall mean the number of Shares subject to the option as specified in the Notice of Award.

**Participant** shall mean the person to whom the option is granted as specified in the Notice of Award.

**Plan** shall mean the Company's 2007 Long-Term Incentive Plan.

**Service** shall mean Participant's performance of services for the Company (or any Subsidiary) in the capacity of an Employee, a Non-Employee Director or a Consultant.

**Shares** shall mean the common shares of the Company and such other securities as may become the subject of Awards, or become subject to Awards, pursuant to an adjustment made under Section 4(b) of the Plan.

**Subsidiary** shall mean a subsidiary company as defined in Section 424(f) of the Code (with the Company being treated as the employer corporation for purposes of this definition).

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## 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, 2007

By: /s/ Robert J. Capetola

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

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## 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, 2007

By: /s/ John G. Cooper

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

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## 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, 2007 (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, 2007

By: /s/ Robert J. Capetola

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

Date: August 9, 2007

By: /s/ John G. Cooper

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John G. Cooper.  
Title: 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 us and will be retained by us 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.

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