

DISCOVERY LABORATORIES INC /DE/  
Form 10-Q  
November 08, 2007

**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 September 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  NO

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

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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 November 6, 2007, 86,590,393 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

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## Table of Contents

		Page
<b>PART I - FINANCIAL INFORMATION</b>		
Item 1.	Financial Statements	1
<b>CONSOLIDATED BALANCE SHEETS</b>		
	As of September 30, 2007 (unaudited) and December 31, 2006	1
<b>CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)</b>		
	For the Three Months Ended September 30, 2007 and 2006	
	For the Nine Months Ended September 30, 2007 and 2006	2
<b>CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)</b>		
	For the Nine Months Ended September 30, 2007 and 2006	3
	Notes to Consolidated Financial Statements	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	25
Item 4.	Controls and Procedures	26
<b>PART II - OTHER INFORMATION</b>		
Item 1.	Legal Proceedings	26
Item 1A.	Risk Factors	27
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 3.	Defaults Upon Senior Securities	27
Item 4.	Submission of Matters to a Vote of Security Holders	27
Item 5.	Other Information	27
Item 6.	Exhibits	27
	Signatures	28

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 variant 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; 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®; 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 and profitably develop and market our products;
- risks relating to our research and development activities, which are time-consuming, costly and involve pre-clinical studies, clinical trials and other studies, and the risk that such trials and studies may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for approval of 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;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file or limit approval to particular indications or other label limitations;
- the risk 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 may not have successfully resolved the Chemistry, Manufacturing and Controls (CMC) and other cGMP-related matters at our manufacturing operations in Totowa, New Jersey, with respect to Surfaxin and our other Surfactant Replacement Therapies (SRT) presently under development, including those identified in connection with our April 2006 process validation stability failures and matters noted by the FDA in its inspectional reports on Form FDA 483;

- risks that our recently submitted formal response to the April 2006 Approvable Letter will not satisfy the FDA;
- risks relating to our own drug manufacturing operations and the 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 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 relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- 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, and 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)*

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 18,831	\$ 26,173
Restricted cash	646	829
Available-for-sale securities	13,609	—
Prepaid expenses and other current assets	298	565
<b>Total Current Assets</b>	<b>33,384</b>	<b>27,567</b>
Property and equipment, net	7,186	4,794
Deferred financing costs and other assets	1,778	2,039
<b>Total Assets</b>	<b>\$ 42,348</b>	<b>\$ 34,400</b>
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,819	\$ 5,953
Capitalized leases and note payable, current portion	2,146	2,015
<b>Total Current Liabilities</b>	<b>8,965</b>	<b>7,968</b>
Loan payable, non-current portion, including accrued interest	9,452	8,907
Capitalized leases and note payable, non-current portion	2,768	2,687
Other liabilities	895	516
<b>Total Liabilities</b>	<b>22,080</b>	<b>20,078</b>
Stockholders' Equity:		
Common stock, \$0.001 par value; 180,000 shares authorized; 84,995 and 69,871 shares issued; and 84,681 and 69,558 shares outstanding at September 30, 2007 and December 31, 2006, respectively.	85	70
Additional paid-in capital	299,556	265,604
Accumulated deficit	(276,339)	(248,298)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Other comprehensive income	20	—
<b>Total Stockholders' Equity</b>	<b>20,268</b>	<b>14,322</b>
<b>Total Liabilities &amp; Stockholders' Equity</b>	<b>\$ 42,348</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)*

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenue	\$ -	\$ -	\$ -	\$ -
Expenses:				
Research and development	6,184	5,204	18,400	18,728
General and administrative	3,147	2,723	9,366	15,429
Restructuring charge	—	—	—	4,805
Total expenses	9,331	7,927	27,766	38,962
Operating loss	(9,331)	(7,927)	(27,766)	(38,962)
Other income / (expense):				
Interest and other income	457	291	1,321	1,468
Interest and other expense	(473)	(362)	(1,596)	(994)
Other income / (expense), net	(16)	(71)	(275)	474
Net loss	\$ (9,347)	\$ (7,998)	\$ (28,041)	\$ (38,488)
Net loss per common share - Basic and diluted	\$ (0.11)	\$ (0.13)	\$ (0.35)	\$ (0.62)
Weighted average number of common shares outstanding - basic and diluted	84,642	62,312	79,485	61,703

*See notes to consolidated financial statements*

**DISCOVERY LABORATORIES, INC. AND SUBSIDIARY****Consolidated Statements of Cash Flows**

(Unaudited)

*(in thousands)*

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
Cash flows from operating activities:		
Net loss	\$ (28,041)	\$ (38,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,212	685
Stock-based compensation and 401(k) match	3,743	4,891
Loss on disposal of property and equipment	3	—
Changes in:		
Prepaid expenses and other current assets	233	282
Accounts payable and accrued expenses	866	(673)
Other assets	(149)	2
Other liabilities and accrued interest on loan payable	924	383
Net cash used in operating activities	(21,209)	(32,918)
Cash flows from investing activities:		
Purchase of property and equipment	(3,163)	(967)
Restricted cash	183	(183)
Purchases of marketable securities	(26,800)	(4,631)
Proceeds from sales or maturity of marketable securities	13,211	7,884
Net cash (used in) / provided by investing activities	(16,569)	2,103
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	30,224	2,800
Equipment financed through capital lease obligation	5,509	1,130
Principal payments under capital lease obligation	(5,297)	(1,232)
Net cash provided by financing activities	30,436	2,698
Net decrease in cash and cash equivalents	(7,342)	(28,117)
Cash and cash equivalents - beginning of period	26,173	47,010
Cash and cash equivalents - end of period	\$ 18,831	\$ 18,893
Supplementary disclosure of cash flows information:		
Interest paid	\$ 511	\$ 964
Non-cash transactions:		
Unrealized gain/(loss) on marketable securities	20	2

*See notes to consolidated financial statements*

**Notes to Consolidated Financial Statements (unaudited)**

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

**The Company**

Discovery Laboratories, Inc. (referred to in these Notes as “we”, “us” and “our”) is a biotechnology company developing its 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), Intensive Care Unit (ICU) and other hospital settings, to treat conditions for which 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 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 connection with this NDA, we recently submitted our formal response to a second Approvable Letter that we received from the FDA in April 2006. If the FDA deems our submission to be a complete response, we anticipate a six-month review period, with a target potential approval date in the second quarter of 2008. 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 Acute Respiratory Failure (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 (CF), chronic obstructive pulmonary disease (COPD), asthma, Acute Respiratory Distress Syndrome (ARDS) and other debilitating respiratory conditions.

We have implemented a business strategy that includes: (i) ongoing efforts intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States; (ii) preparing for the potential approval and commercial launch of Surfaxin for RDS in the United States by (A) expanding our existing Medical Affairs organization to support increased educational and scientific activities, and (B) strategic planning for commercial capabilities to execute the launch of Surfaxin in the United States, if approved; (iii) 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 (Chrysalis), a division of Philip Morris USA Inc.; (iv) continued investment in enhancements to our quality systems and manufacturing capabilities, including our operations in Totowa, New Jersey (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 (v) 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 interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine month periods ended September 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 Policies and Recent Accounting Pronouncements**

### *Accounting Policies*

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.

In September 2006, the FASB issued SFAS No.157, "Fair Value Measurements" (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. The standard requires expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 will be effective for the Company's fiscal year beginning January 1, 2008. The Company is currently reviewing the effect SFAS 157 will have on its 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 \$9.3 million and \$28.0 million for the three months and nine months ended September 30, 2007, respectively, and \$8.0 million and \$38.5 million for the three months and nine months ended September 30, 2006, respectively. 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**

Our stock-based employee compensation plans (Plans) are 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:

	September 30, 2007	September 30, 2006
Expected volatility	97%	101%
Expected term	4 and 5 years	5 years
Risk-free rate	4.6%	5.0%
Expected dividends	—	—

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
(in thousands)				
Research & Development	\$ 319	\$ 353	\$ 1,109	\$ 1,255
General & Administrative	737	567	2,343	2,878
Total	\$ 1,056	\$ 920	\$ 3,452	\$ 4,133

As of September 30, 2007, there was \$7.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average vesting period of 2.01 years.

As of September 30, 2007, 57,123 phantom restricted stock awards were issued and outstanding under our Amended and Restated 1998 Stock Incentive Plan (1998 Plan) and 57,123 shares were reserved for future issuance. Effective as of October 30, 2007, to replace the shares of phantom stock previously granted to each such grantee under the 1998 Plan, we entered into Stock Issuance Agreements (Agreements) pursuant to which the then-eligible grantees received in the aggregate 56,660 restricted shares of common stock. Under the Agreements, restricted shares are subject to a vesting schedule whereby such shares will fully vest on the date that our first drug product first becomes widely commercially available, as determined by management. Prior to such date, a grantee's shares are non-transferable and subject to automatic cancellation upon the termination of such grantee's employment for any reason.



## 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 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 an October 2007 draw-down pursuant to our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group (see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources") that resulted in \$5.0 million of gross proceeds, and before taking into account any additional amounts that may be potentially available through our CEFF, any potential strategic collaborations, and any potential financings, we believe that our current working capital is sufficient to meet planned activities through mid 2008. Use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of our common stock that we may issue under the CEFF (currently not more than approximately 5.2 million shares). In addition, if on any trading day during the eight trading day pricing period for a draw down, the volume weighted average price of our common stock (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 draw-down period, no shares will be issued with respect to that trading day and the total amount of the draw down for that pricing period will be reduced for each such trading day 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 for the remainder of 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 of these events, to lower our cost structure and to 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 the staff reductions and 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 September 30, 2007, the remaining balance of the unpaid restructuring charge was \$0.5 million, which was included in accounts payable and accrued expenses.



**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 a \$12.5 million credit facility (Facility) to fund our capital programs. Under the Facility, \$9 million was made available immediately (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 \$4.0 million of the Facility was drawn to fund the prepayment 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 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 prepayment 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 prepayment, 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 agreed to subordinate its security interest in the Supplemental Collateral (which does not include financed property and equipment) to the security interest in the same collateral that we previously granted to PharmaBio.

As of September 30, 2007, approximately \$4.9 million was outstanding under the secured credit facility with Merrill Lynch and \$3.5 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 September 30, 2007, \$9.5 million was outstanding on this loan, which was comprised of \$8.5 million of principal and \$1.0 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 and filed an opening brief on July 2, 2007. Defendants filed their opening brief on August 6, 2007, and Plaintiffs filed their reply brief on August 20, 2007.

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.

#### **Note 11 - Subsequent Event**

In October 2007, we completed a financing pursuant to the CEFF resulting in proceeds of \$5 million from the issuance of 1,909,172 shares of our common stock at an average price per share, after the applicable discount, of \$2.62.

## **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), Intensive Care Unit (ICU) and other hospital settings, to treat conditions for which 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 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 connection with this NDA, we recently submitted our formal response to a second Approvable Letter that we received from the FDA in April 2006. If the FDA deems our submission to be a complete response, we anticipate a six-month review period, with a target potential approval date in the second quarter of 2008. 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 Acute Respiratory Failure (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 (CF), chronic obstructive pulmonary disease (COPD), asthma, Acute Respiratory Distress Syndrome (ARDS) and other debilitating respiratory conditions.

We have implemented a business strategy that includes:

- ongoing efforts intended to gain regulatory approval to market Surfaxin for the prevention of RDS in premature infants in the United States. We recently submitted our formal response to the Approvable Letter that we received from the FDA in April 2006. Assuming that the FDA accepts our submission as a complete response, we anticipate that the FDA will designate our submission as a Class 2 submission, thereby allowing for a six-month review period with a target approval date under the Prescription Drug User Fee Act (PDUFA) in the second quarter of 2008;
- preparing for the potential approval and commercial launch of Surfaxin for RDS in the United States by (i) expanding our existing Medical Affairs organization to support increased educational and scientific activities, and (ii) strategic planning for commercial capabilities to execute the launch of Surfaxin in the United States, if approved;
- 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, New Jersey (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 September 30, 2007, we had an accumulated deficit of \$276.3 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 September 30, 2007, we had: (i) cash and marketable securities of \$33.1 million; (ii) approximately 7.1 million shares potentially available for issuance (up to a maximum of \$40.5 million) under our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, 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) \$9.5 million outstanding (\$8.5 million principal and \$1.0 million of accrued interest as of September 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) \$4.9 million debt outstanding under a \$12.5 million capital equipment financing arrangement with Merrill Lynch, of which approximately \$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 nine months ended September 30, 2007 were \$6.2 million and \$18.4 million, respectively. Research and development expenses for the three and nine months ended September 30, 2006 were \$5.2 million and \$18.7 million, respectively. These costs are charged to operations as incurred and are tracked by category rather than by project. Research and development costs consist primarily of expenses associated with research, 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 anticipated commercial drug supply. Manufacturing development activities include: (1) costs associated with our manufacturing operations in Totowa, New Jersey (which we acquired from our then-contract manufacturer, Laureate Pharma, Inc. (Laureate) in December 2005) to support the production of clinical and anticipated commercial drug supply for 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, remediation of our related manufacturing issues and such activities associated with obtaining 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 obtaining 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 nine months ended September 30, 2007 and 2006:

<i>( in thousands)</i>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Research and Development Expenses:</b>				
Manufacturing development	\$ 3,141	\$ 2,341	\$ 8,408	\$ 7,732
Unallocated development - clinical and regulatory operations	1,994	1,753	6,329	6,291
Direct pre-clinical and clinical program expenses	1,049	1,110	3,663	4,705
<b>Total Research &amp; Development Expenses</b>	<b>\$ 6,184</b>	<b>\$ 5,204</b>	<b>\$ 18,400</b>	<b>\$ 18,728</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 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, manufactured to our specifications and on commercially reasonable terms;
- 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;
- Whether we have successfully resolved the chemistry, manufacturing and controls (CMC) and cGMP-related matters at our manufacturing operations in Totowa, New Jersey with respect to Surfaxin, including those matters identified in connection with the April 2006 process validation stability failures and those noted by the FDA in its inspectional reports on Form FDA 483;



Successful manufacture at our manufacturing operations in Totowa 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.
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;

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;
- Failure of a product candidate to demonstrate effectiveness; 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, CF, 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 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.

**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 restructuring, 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 any 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 September 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 September 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 herein and those contained in the "Risk Factors" section 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 and PICU, we are conducting several NICU and PICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal and pediatric 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 Chemistry, Manufacturing and Controls (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. As a result of our investigation, we identified a most probable root cause, and executed a corrective action and preventative action (CAPA) plan.

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 obtained from the FDA, in February 2007, we completed the manufacture of three new Surfaxin process validation batches. These process validation batches have been, and will continue to be, 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 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Under this comprehensive testing protocol, these process validation batches have demonstrated acceptable stability through six months and continue to be monitored.

In October 2007, we completed the projects and compiled the additional data that we thought necessary to address the outstanding CMC issues identified in the Approvable Letter and submitted our formal response to FDA. Those projects were developed based on the guidance that we received at our December 2006 meeting with the FDA. Our formal response also included the six-month stability data from our new process validation batches. We expect that the FDA will advise us in mid-November whether it has accepted our submission as a complete response and provide a review classification that determines the targeted review timeframe. Assuming that our submission is deemed complete, we anticipate that the FDA will designate our submission as a Class 2 submission, thereby allowing for a six-month review period with a target approval date under PDUFA in the second quarter of 2008.

We voluntarily withdrew in June 2006 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 by 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 is being 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. Initiation of our Phase 2 clinical program is anticipated in the first half of 2008.

### SRT for Critical Care and Hospital Indications

We are also evaluating the potential development of our proprietary precision-engineered SRT to address respiratory disorders such as CF, ALI, 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:

### Current Manufacturing Capabilities

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.

16

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In April 2006, ongoing analysis of our initial 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 (CAPA) plan to remediate the related manufacturing issues.

In anticipation of our December 2006 meeting with the FDA, we submitted an information package that covered certain of the key CMC matters identified in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation and our efforts to remediate the related manufacturing issues. Following our meeting with the FDA, and consistent with the guidance obtained at the meeting, in February 2007, we completed the manufacture of three new Surfaxin process validation batches. These process validation batches have been, and will continue to be, subjected to ongoing comprehensive stability testing under an established protocol that complies with ICH guidelines and, to date, have demonstrated acceptable stability through six months. For a discussion of the status of the new Surfaxin process validation batches and our recent response to the Approvable Letter, please see “MD&A - Research and Development, Surfaxin for the Prevention of RDS in Premature Infants.”

Our manufacturing strategy includes continuing investment in our analytical and quality systems to support our manufacturing and development activities. We recently completed construction of a new analytical and development laboratory in our Warrington, Pennsylvania corporate headquarters. When fully operational, the new laboratory will consolidate all of the analytical, quality and development activities that are presently located in Doylestown, Pennsylvania and Mountain View, California. The laboratory will expand our capabilities by providing additional capacity to conduct analytical testing and opportunities to leverage our newly consolidated professional expertise across a broad range of projects. Our analytical testing activities predominantly involve release and stability testing of raw materials as well as commercial and clinical drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our product candidates.

#### Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operation in Totowa, New Jersey that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential worldwide demand for our RDS, ARF and BPD programs and all of our anticipated production requirements for Aerosurf.

We view our acquisition of manufacturing operations in Totowa 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 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 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. 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, New Jersey facility.

See the applicable risks discussed herein and in the “Risk Factors” section 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 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 nine months ended September 30, 2007 were \$9.3 million (or \$0.11 per share) and \$28.0 million (or \$0.35 per share), respectively. The net loss for the three and nine months ended September 30, 2006 were \$8.0 million (or \$0.13 per share) and \$38.5 million (or \$0.62 per share), respectively.

**Revenue**

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

18

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## Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2007 were \$6.2 million and \$18.4 million, respectively. Research and development expenses for the three and nine months ended September 30, 2006 were \$5.2 million and \$18.7 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 nine months ended September 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 nine months ended September 30, 2007 were \$3.1 million and \$8.4 million, respectively, as compared to \$2.3 million and \$7.7 million for the three and nine months ended September 30, 2006, respectively. Manufacturing development expenses for 2007 primarily consist of (i) costs associated with our manufacturing operations in Totowa, New Jersey 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 nine months ended September 30, 2007 were \$3.1 million and \$10.0 million, respectively, as compared to \$2.9 million and \$11.0 million for the three and nine months ended September 30, 2006, respectively. Research and development expenses for 2007 primarily include: (i) costs associated with obtaining data and other information necessary for our formal response to the Surfaxin Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin for ARF in children up to two years of age; and (iii) development activities related to Aerosurf. The decrease in expenses for the nine months ended September 30, 2007 compared to the same period last year primarily reflects personnel and related costs incurred in 2006, in anticipation of the potential approval and commercial launch of Surfaxin for the prevention of RDS in premature infants, that were later reduced as a result of staff reductions and a 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 nine months ended September 30, 2007 were \$3.1 million and \$9.4 million, respectively, as compared to \$2.7 million and \$15.4 million for the three and nine months ended September 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**

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 of these events, 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. The reduction in workforce, which included three senior executives, 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. 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 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 September 30, 2007, the remaining balance of the unpaid restructuring charge totals \$0.5 million, which is included in accounts payable and accrued expenses.

## **Other Income and (Expense)**

Other income and (expense) for the three and nine months ended September 30, 2007 were (\$16,000) and (\$257,000) million, respectively. Other income and (expense) for the three and nine months ended September 30, 2006 were (\$71,000) and \$474,000 million, respectively.

Interest and other income for the three and nine months ended September 30, 2007 was \$0.5 million and \$1.3 million, respectively, as compared to \$0.3 million and \$1.5 million for the three and nine months ended September 30, 2006, respectively. The increase for the three months ended September 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 nine months ended September 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 nine months ended September 30, 2007 was \$0.5 million and \$1.6 million, respectively, as compared to \$0.4 million and \$1.0 million for the three and nine month ending September 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 (currently not more than approximately 5.2 million shares). We anticipate using the CEFF, when available, to support working capital needs in 2007.

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

As of September 30, 2007, we had cash, cash equivalents, restricted cash and marketable securities of \$33.1 million, as compared to \$27.0 million as of December 31, 2006. The increase is primarily due to: (i) in April 2007, a registered direct offering of 14,050,000 shares of our common stock to select institutional investors. The shares were priced at \$2.15 per share resulting in gross proceeds of \$30.2 million (\$28.1 million net). This offering was made pursuant to our October 2005 universal shelf registration statement; (ii) proceeds of \$2.0 million from a financing pursuant to the CEFF (discussed below); and (iii) \$1.5 million from the use of the secured credit facility with Merrill Lynch; offset by (iv) \$25.9 million used in operating activities, purchases of capital expenditures and principal payments on capital lease arrangements.

In October 2007, we completed a financing pursuant to the CEFF resulting in proceeds of \$5 million from the issuance of 1,909,172 shares of our common stock at an average price per share, after the applicable discount, of \$2.62.

### **Committed Equity Financing Facility (CEFF)**



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 entered with Kingsbridge 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 Securities and Exchange Commission (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 for that pricing period will be reduced for each such trading day by one-eighth of the draw down amount that 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 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.

In October 2007, we completed a financing pursuant to the CEFF resulting in proceeds of \$5 million from the issuance of 1,909,172 shares of our common stock at an average price per share, after the applicable discount, of \$2.62.

As of October 12, 2007, there were approximately 5.2 million shares available for issuance under the CEFF (up to a maximum of \$35.5 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.

**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.

### **Investments in Property and Equipment**

In October, we completed the construction of a new research and analytical laboratory in our Warrington, Pennsylvania corporate headquarters. The new laboratory will consolidate the analytical and development activities that are presently located in Doylestown, Pennsylvania, and Mountain View, California, including analytical testing of raw materials and commercial and clinical drug product supply, as well as research and development of our aerosol SRT and other novel formulations. The consolidation of scientific and analytical resources into one facility will allow us to leverage professional and scientific expertise and improve both operational efficiency and financial economics.

The investment in the new laboratory will be \$3.3M (\$2.6M is reflected on the balance sheet as property and equipment at September 30, 2007 and the remainder is anticipated in the fourth quarter 2007). We anticipate that approximately 95% of the total project will be financed utilizing: (i) our existing secured credit facility with Merrill Lynch; (ii) \$650,000 from the Commonwealth of Pennsylvania (including a \$500,000 loan from the Machinery and Equipment Loan Fund and grants of up to \$150,000 through the Opportunities Grant Program and Customized Job Training Funds); and (iii) a \$400,000 landlord contribution under our existing lease agreement.

### **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 in 2001. In 2004 and in October 2006, we amended and restated the loan documents and restructured the loan. As a result of the restructuring, we now have a loan with PharmaBio in the principal amount of \$8.5 million that matures on 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 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 PharmaBio 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 September 30, 2007, the outstanding balance under the loan was \$9.5 million (\$8.5 million of pre-restructured principal and \$1.0 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 a \$12.5 million credit facility (Facility) to fund our capital programs. Under the Facility, \$9 million was made available immediately (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 \$4.0 million of the Facility was drawn to fund the prepayment 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 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 prepayment 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 prepayment, 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, Merrill Lynch and PharmaBio entered into an Intercreditor Agreement under which Merrill Lynch agreed to subordinate its security interest in the Supplemental Collateral (which does not include financed property and equipment) to the security interest in the same collateral that we previously granted to PharmaBio (discussed above).

As of September 30, 2007, approximately \$4.9 million was outstanding under the Facility (\$2.1 million classified as current liabilities and \$2.8 million as long-term liabilities) and \$3.5 million remained available for use, subject to the conditions of the Facility. In the quarter ending September 30, 2007, we used \$1.3 million under this Facility, primarily to finance the new laboratory.

Previously, our capital financing arrangements had been primarily with the Life Science and Technology Finance Division of GECC. Pursuant to a Master Security Agreement, we purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently financed those purchases through GECC.

### **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, New Jersey, that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements. The lease expires in December 2014 with total aggregate payments since inception of the lease 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 expired in August 2007 on a monthly basis. We are currently consolidating the activities at this location into our new laboratory space in Warrington, Pennsylvania and expect to terminate this lease in the first half of 2008.

We lease office and laboratory space in Mountain View, California. The facility is 16,800 square feet and houses aerosol and formulation development activities. We are currently consolidating these activities into our new laboratory space in Warrington, Pennsylvania. The lease expires in June 2008 with total aggregate payments since inception of the lease 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 and filed an opening brief on July 2, 2007. Defendants filed their opening brief on August 6, 2007, and Plaintiffs filed their reply brief on August 20, 2007.

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 nine months ended September 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 nine months ended September 30, 2007.

#### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

#### **ITEM 5. OTHER INFORMATION**

None.

#### **ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

Discovery Laboratories, Inc.  
(Registrant)

Date: November 8, 2007

By: /s/ Robert J. Capetola

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

Date: November 8, 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.

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	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 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.
4.3	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.
4.4	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.

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| 4.5 | 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. |
| 4.6 | 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.  |
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Exhibit No.	Description	Method of Filing
4.7	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.
4.8	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.
4.9	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.
4.10	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	Stock Issuance Agreement dated as of October 30, 2007	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 30, 2007.
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.