

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

FORM 10-K/A
(Amendment No. 2)

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

For the fiscal year ended December 31, 2009

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)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	The Nasdaq Capital Market
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. YES ☐ NO ☒

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☒

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant computed using the closing price of common equity as reported on The Nasdaq Global Market under the symbol DSCO on June 30, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$126 million. For the purposes of determining this amount only, the registrant has defined affiliates to include: (a) the executive officers named in Part III of this Annual Report on Form 10-K; (b) all directors of the registrant; and (c) each shareholder, if any, that has informed the registrant by March 1, 2009 that it is the beneficial owner of 10% or more of the outstanding shares of common stock of the registrant.

As of November 12, 2010, 206,652,815 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

EXPLANATORY NOTE

We are filing this Amendment No. 2 on Form 10-K/A to our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission (“SEC”) on March 10, 2010 (“Annual Report on Form 10-K”), (i) to amend Item 1A – “Risk Factors” to add to the risk factors previously provided in our Annual Report on Form 10-K additional risk factors related to the restatement of our financial statements, (ii) to amend Item 6 – “Selected Financial Data” and Item 8 – “Financial Statements and Supplementary Data” to restate our audited financial statements for the year ended December 31, 2009 to reflect the reclassification of certain warrants from equity to liabilities, as discussed below, (iii) to make corresponding amendments to Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations” (“MD&A”) and to provide in MD&A additional disclosure with respect to research and development expenses, (iv) to amend Item 9A – “Controls and Procedures” to reflect a reassessment of our disclosure controls and procedures, and internal control over financial reporting, as of December 31, 2009 in light of the restatement of our audited financial statements for the year ended December 31, 2009.

Other than the foregoing, and the new certifications required by Rule 13a-14(a) under the Securities and Exchange Act of 1934 (“Exchange Act”), our Annual Report on Form 10-K is not being amended or updated in any respect. This Amendment No. 2 continues to describe the conditions as of the date of the Annual Report on Form 10-K, and, except as contained herein, we have not modified or updated the disclosures contained in the Annual Report on Form 10-K. This Amendment No. 2 should be read in conjunction with our filings made with the SEC subsequent to the filing of the Annual Report on Form 10-K, including any amendment to those filings.

Restatement of Financial Statements

In connection with a review of our Annual Report on Form 10-K among the Audit Committee of our Board of Directors (the “Audit Committee”), and our management, with the assistance of Ernst & Young LLP (“Ernst & Young”), our independent registered public accounting firm, and our outside legal advisors, the Audit Committee has reassessed the accounting classification of certain warrants that we issued in May 2009 with respect to ASC 815 “Derivatives and Hedging — Contracts in Entity’s Own Equity” (“ASC 815,” formerly known as Emerging Issues Task Force Issue 00-19, “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock”). The review was conducted to respond to certain comments raised by the Staff of the SEC following its periodic review of our Annual Report on Form 10-K.

We have historically accounted for warrants, which prior to May 2009 were issued in private transactions, as equity instruments. Our warrants generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise and without any evaluation of remoteness or probability, ASC 815, as interpreted, establishes a presumption that, in the absence of express language to the contrary, registered warrants may be subject to net cash settlement, as it is not within our absolute control to provide freely-tradable shares in all circumstances.

After extensive discussion, the Audit Committee, together with our management and in consultation with Ernst & Young and our outside legal advisors, determined that, notwithstanding the highly-remote and theoretical possibility of net cash settlement, the warrants identified above should have been recorded as liabilities, measured at fair value calculated using the Black Scholes option pricing model on the date of issue, with changes in the fair values recognized in our quarterly statement of operations in our quarterly financial reports. Accordingly, the Audit Committee also concluded on November 8, 2010 that our previously-filed consolidated financial statements for the year ended December 31, 2009 on Form 10-K; Ernst & Young’s reports on the financial statements and the effectiveness of internal control over financial reporting for the year ended December 31, 2009; each of the consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009; and all related earnings releases and similar communications that we issued with respect to the foregoing, should no longer be relied upon. As a result, we are restating our previously-filed consolidated financial statements for the year ended December 31, 2009 on Form 10-K. We do not plan to amend

our consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009.

The restatements will have no impact on amounts previously reported for Assets; Revenues; Operating Expenses; Cash Flows; Loans, Equipment Loan and Accounts Payables; and Contractual Obligations. The restatements will have no effect on our development programs, including Surfaxin®, anticipated development milestones, business strategy or operations. *See* Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in this Amendment No. 2.

In light of the restatement, we have also determined that as of December 31, 2009 our disclosure controls and procedures were not effective, and that we did not maintain effective internal control over financial reporting due to a material weakness related to the initial classification and subsequent accounting of registered warrants as either liabilities or equity instruments. *See*, “Item 9A Controls and Procedures.”

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 Amendment No. 2 contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 (“Securities Act”) and Section 21E of the Exchange Act. The forward-looking statements include all matters that are not historical facts. Forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements in this report are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those set forth under “Risk Factors” and “Management’s Discussion and Analysis of Financial Conditions and Results of Operations” in the Annual Report on Form 10-K and elsewhere in, or incorporated by reference into, the Annual Report on Form 10-K, as amended, including this Amendment No. 2.

Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation 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.

DISCOVERY LABORATORIES, INC.

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For the Year Ended December 31, 2009**

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ITEM 1A. RISK FACTORS.

In addition to the risk factors and other information concerning risks set forth in our Annual Report on Form 10-K and in the documents incorporated by reference in our Form 10-K and this Amendment No. 2, you should carefully consider the following risks before deciding to invest in shares of our common stock. If any of the following risks actually occurs, our business prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you could lose all or part of your investment.

The restatement of our historical financial statements has already consumed a significant amount of our time and resources and may have a material adverse effect on our business and stock price.

As described earlier, we have restated our consolidated financial statements. The restatement process was highly time and resource-intensive and involved substantial attention from management and significant legal and accounting costs. Although we have now completed the restatement, we cannot guarantee that we will have no inquiries from the SEC or The NASDAQ Capital Market® (“Nasdaq Capital Market”) regarding our restated financial statements or matters relating thereto.

Any future inquiries from the SEC as a result of the restatement of our historical financial statements will, regardless of the outcome, likely consume a significant amount of our resources in addition to those resources already consumed in connection with the restatement itself.

Further, many companies that have been required to restate their historical financial statements have experienced a decline in stock price and stockholder lawsuits related thereto.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

As described elsewhere in this Amendment No. 2, in connection with the restatement process, we identified a material weakness with regard to accounting for warrant instruments in our internal control over financial reporting, specifically with regard to our prior interpretation of ASC 815, as it related to the initial classification and subsequent accounting of registered warrants as either liabilities or equity instruments dating back to May 2009. Upon a reassessment of those financial instruments, in light of GAAP as currently interpreted, we determined that we should have accounted for certain warrant instruments as liabilities instead of equity. Given this material weakness with regard to warrants, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2009.

Since the determination regarding this material weakness, we plan to devote significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and intelligently apply developments in accounting, we plan to enhance these processes to better evaluate our research and understanding of the nuances of increasingly complex accounting standards. Our plans include the following: enhanced access to accounting literature, research materials and documents; and increased communication among our legal and finance personnel and third party professionals with whom to consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time and we can offer no assurance that these initiatives will ultimately have the intended effects. Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and Nasdaq, we could

face severe consequences from those authorities. In either case, there could result a material adverse affect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

PART II

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth in this Item 6 give effect to the restatements described in “Item 7 - Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in Note 2 to our consolidated financial statements and should be read in conjunction therewith. The consolidated statement of operations data for the years ended December 31, 2009 (as restated), 2008 and 2007 and consolidated balance sheet data as of December 31, 2009 (as restated) and 2008 have been derived from audited consolidated financial statements included as part of this Amendment No. 2. The consolidated statement of operations data for the years ended December 31, 2006 and 2005 and consolidated balance sheet data as of December 31, 2007 and 2006 and 2005 are derived from audited financial statements not included in this Amendment No. 2.

Consolidated Statement of Operations Data: <i>(in thousands, except per share data)</i>					
	For the year ended December 31,				
	2009 (As Restated)	2008	2007	2006	2005
Revenues from collaborative agreements	\$ -	\$ 4,600	\$ -	\$ -	\$ 134
Operating Expenses:					
Research and development	19,077	26,566	26,200	23,716	24,137
General and administrative	10,120	16,428	13,747	18,386	18,505
Restructuring charges	-	-	-	4,805	-
In-process research and development	-	-	-	-	16,787
Total expenses(1)	29,197	42,994	39,947	46,907	59,429
	(29,197)	(38,394)	(39,947)	(46,907)	(59,429)
Change in fair value of common stock warrant	369	-	-	-	-
Other (expense) / income	(1,043)	(712)	(58)	574	391
Net loss	<u>\$ (29,871)</u>	<u>\$ (39,106)</u>	<u>\$ (40,005)</u>	<u>\$ (46,333)</u>	<u>\$ (58,904)</u>
Net loss per common share - basic and diluted	\$ (0.26)	\$ (0.40)	\$ (0.49)	\$ (0.74)	\$ (1.09)
Weighted average number of common shares outstanding	115,200	98,116	81,731	62,767	54,094
⁽¹⁾ Included in the net loss for the years ended December 31, 2009, 2008, 2007 and 2006 were non-cash charges for stock-based compensation for employees in accordance with ASC Topic 718 of \$2.7 million, \$4.6 million, \$5.3 million and \$5.5 million, respectively.					

Consolidated Balance Sheet Data: <i>(in thousands)</i>					
	December 31,				
	2009 (As Restated)	2008	2007	2006	2005
Cash and investments	\$ 15,741	\$ 24,792	\$ 53,007	\$ 26,402	\$ 50,908
Working capital (before common stock warrant liability)	176	15,551	43,149	18,999	33,860
Total assets	21,403	32,889	62,744	34,400	56,008
Long-term obligations, less current portion	1,118	12,090	13,494	12,110	3,562
Total stockholder’s equity	\$ 1,296	\$ 10,933	\$ 38,781	\$ 14,322	\$ 34,838

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

RESTATEMENT OF PREVIOUSLY-ISSUED CONSOLIDATED FINANCIAL STATEMENTS

In this Amendment No. 2, we have restated our previously-issued consolidated financial statements and related disclosures for the year ended December 31, 2009 and each of the quarterly consolidated financial statements on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009 to reclassify warrants that we issued in May 2009, based on a reassessment of the applicable accounting guidance.

In accordance with our interpretation of applicable accounting guidance contained in Accounting Standards Codification (ASC) Topic 815 "Derivatives and Hedging — Contracts in Entity's Own Equity" (ASC 815) (formerly known as Emerging Issues Task Force Issue 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock"), we have historically accounted for warrants as equity instruments. Prior to May 2009, we issued warrants in private transactions. In May 2009, we issued warrants in connection with a registered offering. To respond to certain comments raised by the Staff of the Securities and Exchange Commission ("SEC") following its periodic review of our 2009 Annual Report on Form 10-K, the Audit Committee of our Board of Directors (the "Audit Committee"), and our management, with the assistance of Ernst & Young LLP ("Ernst & Young"), our independent registered public accounting firm, and our outside legal advisors, reassessed the accounting classification of the May 2009 registered warrants with respect to ASC 815.

The May 2009 warrants provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise, ASC 815, as interpreted, establishes a presumption that, in the absence of express language to the contrary, registered warrants may be subject to net cash settlement, as it is not within our absolute control to provide freely-tradable shares in all circumstances. After extensive discussion, our management, Ernst & Young, and our outside legal advisors concluded that, although the interpretation and applicability of ASC 815 as it relates to registered warrants is complex and subject to varying interpretations, it should be applied based on a strict reading of the authoritative literature.

Applying such a strict reading, the Audit Committee, together with management and in consultation with Ernst & Young and our outside legal advisors, determined that, notwithstanding the highly-remote and theoretical possibility of net cash settlement, the warrants that we issued in May 2009 in connection with a registered offering should have been recorded as liabilities, measured at fair value on the date of issue, with subsequent changes in the fair values recognized in our quarterly statement of operations. Accordingly, the Audit Committee also concluded on November 8, 2010 that our previously-filed consolidated financial statements for the year ended December 31, 2009 on Form 10-K; Ernst & Young's reports on the financial statements and the effectiveness of internal control over financial reporting for the year ended December 31, 2009; each of the consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009; and all related earnings releases and similar communications that we issued with respect to the foregoing, should no longer be relied upon. As a result, we are amending and restating our previously-filed consolidated financial statements for the year ended December 31, 2009 on Form 10-K. We do not plan to amend our consolidated financial statements included in our Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009.

The restatements reflect the reclassification of the warrants from equity to a liability in the following amounts, which represents the fair value of the warrants, as of the issuance dates, calculated using the Black-Scholes option pricing model.

Issuance Date	Number of Warrants Issued	Exercise Price	Expiration of Warrants	Fair Value of Warrants at Issuance Date (In thousands)
May 13, 2009	7,000,000	\$1.15	May 13, 2014	\$3,560

The revaluation of the fair value of warrants at each subsequent balance sheet date results in a change in the carrying value of the liability, which change is recorded as “Change in fair value of common stock warrant liability” in the consolidated statement of operations. The net effect of these changes for year ended December 31, 2009, and for each of the quarterly consolidated financial statements on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009 are as follows:

Reporting Period	Income (Loss) Resulting from Change in Fair Value of Common Stock Warrant Liability (In thousands)	Net Effect on Loss Per Share
Annual		
Year ended December 31, 2009	\$ 369	\$ —
Interim (Unaudited)		
Quarter ended June 30, 2009	(1,323)	(0.01)
Quarter ended September 30, 2009	(1,662)	(0.01)
Quarter ended December 31, 2009	3,354	0.03

We have not amended our previously-filed Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009 to reflect the restatements described in this Amendment No. 2, and thus the financial statements and related financial statement information contained in those reports should no longer be relied upon. Throughout this Amendment No. 2, all amounts presented from prior periods and prior period comparisons that have been revised are labeled as “restated” and reflect the balances and amounts on a restated basis.

INTRODUCTION

Management’s discussion and analysis of financial condition and results of operations (MD&A) is provided as a supplement to the accompanying consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our consolidated financial statements. See, “Item 15 – Exhibits and Financial Statement Schedules.”

The information below has been adjusted solely to reflect the impact of the restatement of our financial results, which is more fully described above and in Note 2 to the consolidated financial statements included in this Amendment No. 2, and to provide in MD&A additional disclosure with respect to research and development expenses, and does not reflect any subsequent information or events occurring after the date of the filing of our Annual Report on Form 10-K or update any disclosure herein to reflect the passage of time since the date of such filings.

Our discussion is organized as follows:

- **Company Overview and Business Strategy:** this section provides a general description of our company and business plans.
- **Critical Accounting Policies:** this section contains a discussion of the accounting policies that we believe are important to our financial condition and results of operations and that require the exercise of judgment and use of estimates on the part of management in their application. In addition, all of our significant accounting policies, including the critical accounting policies and estimates, are discussed in Note 3 to the accompanying consolidated financial statements.

- **Results of Operations:** this section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations, including comparisons of the results for the years ended December 31, 2009, 2008 and 2007.
- **Liquidity and Capital Resources:** this section provides a discussion on our capital resources, future capital requirements, cash flows, committed equity financing facilities, historical financing transactions, outstanding debt arrangements and commitments.

OVERVIEW

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a biotechnology company developing our novel KL₄ proprietary technology, which produces a synthetic, peptide-containing surfactant (KL₄ surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol-generating technology (capillary aerosolization technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL₄ surfactant to the lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of respiratory problems.

We are developing our lead products, Surfaxin[®] (lucinactant), Surfaxin LS[™] and Aerosurf[®], to address the most significant respiratory conditions affecting pediatric populations. Our research and development efforts are currently focused on the management of RDS in premature infants. We believe that the RDS market represents a significant opportunity from both a medical and a business perspective. We further believe that Surfaxin, Surfaxin LS and Aerosurf, have the potential to greatly improve the management of RDS and, collectively, represent the opportunity, over time, to significantly expand the current RDS worldwide annual market.

In addition to our lead products, we plan over time to develop our KL₄ surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. Our KL₄ surfactant is in clinical development to potentially address pediatric patients with Acute Respiratory Failure (ARF) and patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL₄ surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL₄ surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

An important priority is to secure strategic and financial resources to potentially maximize the inherent value in our KL₄ surfactant technology. We would prefer to accomplish our objectives through strategic alliances. With respect to our lead products, we are actively engaged in discussions with potential strategic and/or financial partners, although there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded. With respect to our early stage exploratory programs, our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development.

We have focused our current resources on our lead products, primarily to address the requirements to gain the potential approval of Surfaxin in the United States. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL₄ surfactant technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our pipeline programs.

The reader is referred to, and encouraged to read in its entirety “Item 1 – Business” of this Annual Report on Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL₄ pipeline programs.

As of December 31, 2009, we had cash and cash equivalents of \$15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of \$16.5 million (\$15.1 million net). Also, as of December 31, 2009, our \$10.5 million loan with Quintiles is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan: however, there can be no assurance that any such restructuring will occur. Currently, under our two Committed Equity Financing Facilities (CEFFs), we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. However, as of March 1, 2010, neither CEFF was available because the market price of our common stock price was below the minimum price required to utilize the facility. During 2009, we raised aggregate gross proceeds of \$22.0 million. In May 2009, we completed a registered direct public offering in resulting in gross proceeds of \$11.3 million (\$10.5 million net), and, throughout 2009, we raised an aggregate of \$10.7 million from 10 draw-downs under our CEFFs. *See, “– Committed Equity Financing Facilities (CEFFs)”, and “– Financings Pursuant to Common Stock Offerings.”*

Our future capital requirements depend upon many factors, including the success of our efforts to secure one or more strategic alliances or other collaboration arrangements to support our product development activities and, if approved, commercialization plans. We are currently focused on developing our lead KL₄ surfactant products, Surfaxin LS, Aerosurf and Surfaxin, to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that we will be able to secure strategic partners or collaborators to support and advise our activities, that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements and continue our operations. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates, judgments 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.

We believe the following accounting policies are the most critical for an understanding of our financial condition and results of operations. For further discussion of our accounting policies, *see* “Note 3 – Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements for the year ended December 31, 2009, in Part IV to this Annual Report on Form 10-K.

Revenue recognition under strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. Grant revenue is recorded upon receipt of funds.

Research and development expenses

Research and development costs consist primarily of expenses associated with our personnel, facilities, manufacturing operations, formulation development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

Warrant accounting

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. In compliance with applicable securities law, registered common stock warrants that require the issuance of registered shares upon exercise and do not sufficiently preclude an implied right to cash settlement are accounted for as derivative liabilities. We classify these derivative warrant liabilities on the consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes pricing model to value the derivative warrant liability. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as “Change in the fair value of common stock warrant liability.”

RESULTS OF OPERATIONS

The net loss for the years ended December 31, 2009, 2008 and 2007 was \$29.9 million (or \$0.26 per share), \$39.1 million (or \$0.40 per share), and \$40.0 million (or \$0.49 per share), respectively. Included in the net loss for the years ended December 31, 2009, 2008 and 2007 were stock-based compensation expenses of \$2.7 million (or \$0.02 per share), \$4.6 million (or \$0.05 per share), and \$5.3 million (or \$0.06 per share), respectively. In addition, the net loss for the year ended December 31, 2009 includes \$0.4 million of income from warrant obligations in connection with the restatement of our previously reported financial statements.

Revenue

The company did not record any revenues in 2009 and 2007.

In March 2008, we restructured our December 2005 strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility from Chrysalis for the further development of the capillary aerosolization technology. As part of the restructuring, Chrysalis completed a technology transfer to us, provided development support through June 30, 2008, and also paid us \$4.5 million to support our future development activities, which we recognized as revenue in 2008. See, “Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Philip Morris USA Inc. and Philip Morris Products S.A.”

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. As many of our research and development activities form a foundation for the development of our KL₄ surfactant technology platform, they benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) manufacturing development, (b) development operations, and (c) direct pre-clinical and clinical programs. We also track our research and development expenses by the following categories: (i) salaries and benefits, (ii) contracted services, (iii) rents and utilities, (iv) raw materials and supplies, (v) stock-based compensation and (vi) other.

Research and development expenses for the years ended December 31, 2009, 2008 and 2007 were \$19.1 million, \$26.6 million and \$26.2 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands)

	Year Ended December 31,		
	2009	2008	2007
Research and Development Expenses:			
Manufacturing development	\$ 9,118	\$ 14,165	\$ 11,888
Development operations	7,100	9,113	10,196
Direct pre-clinical and clinical programs	2,859	3,288	4,116
Total Research and Development Expenses ⁽¹⁾	<u>\$ 19,077</u>	<u>\$ 26,566</u>	<u>\$ 26,200</u>

For a description of the clinical programs included in research and development, *see* “– Surfactant Replacement Therapy for Respiratory Medicine.”

Manufacturing Development

Manufacturing development includes the cost of our manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and potential commercial drug supply for our KL₄ surfactant products, in conformance with current good manufacturing practices (cGMP). These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities and analytical services, etc. Additionally, in 2008 costs included activities to address issues identified in an Approvable Letter that we received from the FDA with respect to Surfaxin in May 2008 (May 2008 Approvable Letter).

The decrease in manufacturing development expenses in 2009 as compared to 2008 is primarily due to our efforts in 2009 to conserve financial resources following receipt of the April 2009 Complete Response Letter.

The increase in manufacturing development expenses in 2008 as compared to 2007 is primarily due to: (i) expenditures in 2008 to support our quality assurance and analytical chemistry capabilities, including implementation and validation of analytical methods and quality testing of drug product for our development programs; (ii) activities related to preparation of the Complete Response to the May 2008 Approvable Letter; and (iii) purchases of active ingredients for the production of Surfaxin.

Manufacturing development expenses included charges of \$0.4 million, \$0.8 million and \$0.7 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, respectively.

Development Operations

Development operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our KL₄ surfactant development programs; (ii) medical affairs activities to provide scientific and medical education support in connection with our KL₄ surfactant technology pipeline programs; (iii) design and development for the manufacture of our novel capillary aerosolization systems, including an aerosol generating device, the disposable dose delivery packets and patient interface system necessary to administer Aerosurf for our planned Phase 2 clinical trials and; (iv) pharmaceutical development activities, including development of a lyophilized (dry powder) formulation of our KL₄ surfactant. These costs include personnel, expert consultants, outside services to support regulatory, data management and device development activities, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The decrease in development operations expenses in 2009 as compared to 2008 is primarily due to our efforts in 2009 to conserve financial resources and limit investment in our KL₄ respiratory pipeline programs following receipt of the April 2009 Complete Response Letter. The decrease in development operations expenses in 2008 as compared to 2007 is primarily due to cost reductions resulting from the relocation of our analytical testing and pharmaceutical development activities previously performed at our laboratories located in Doylestown, Pennsylvania, and Mountain View, California, and consolidation of those activities into our new laboratory space in Warrington, Pennsylvania, in the fourth quarter of 2007. The decrease in 2008 from 2007 was partially offset by expenditures in 2008 associated with our medical affairs capabilities, including medical science liaisons and symposiums at key pediatric medical meetings in anticipation of the potential approval and commercial launch of

Surfaxin in May 2008. Expenses associated with medical affairs activities were \$0.6 million, \$2.0 million and \$0.8 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Development operations expenses included charges of \$0.3 million, \$0.7 million and \$0.9 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, respectively.

Direct Pre-Clinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) pre-clinical activities, including toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, clinical drug supply and related external costs such as contract research consultant fees and expenses; (iii) activities related to addressing the items identified in the April 2009 Complete Response Letter; and (iv) activities related to preparation of the Complete Responses (submitted in November 2007 and October 2008, respectively) to an Approvable Letter received from the FDA with respect to Surfaxin in April 2006 (April 2006 Approvable Letter) and the May 2008 Approvable Letter.

Direct pre-clinical and clinical programs expenses in 2009 included: (i) costs associated with activities to address issues identified in the April 2009 Complete Response Letter; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF; and (iii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Surfaxin LS and Aerosurf for RDS in premature infants.

Direct pre-clinical and clinical programs expenses in 2008 and 2007 included: (i) costs associated with preparation of the Complete Responses to the May 2008 Approvable Letter and the April 2006 Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF; and (iii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for RDS in premature infants. The decrease in expenses in 2008 as compared to 2007 is primarily due to our efforts to conserve financial resources following receipt of the May 2008 Approvable Letter.

The decrease in direct pre-clinical and clinical program expenses in 2009 compared to 2008 and 2007 is primarily due to our efforts to conserve financial resources and limit our investment in research and development programs in anticipation of potentially securing a strategic or financial alternative to fund our research and development activities.

Research and Development Expenses by Category

We also track our research and development expenses in major categories as shown in the following table:

	<u>2009</u>	<u>2008</u>	<u>2007</u>
Salaries & Benefits	\$ 8,693	\$ 11,651	\$ 9,808
Contracted Services	4,832	6,378	8,522
Rents & Utilities	1,310	1,628	2,105
Depreciation	1,235	1,511	1,135
Raw Materials & Supplies	1,466	2,241	1,091
Stock-Based Compensation	694	1,503	1,681
All Other	847	1,654	1,858
Total	<u>\$ 19,077</u>	<u>\$ 26,566</u>	<u>\$ 26,200</u>

Year-to-year changes in salaries, benefits and stock-based compensation generally reflect changes in the size and mix of our employee base over time. In the second half of 2007, we increased our workforce in anticipation of the potential commercial launch of Surfaxin in 2008 and, with the prospect of generating revenues, a potential acceleration of our investment in our pipeline programs. We maintained our employee base at approximately the

same level throughout 2008. Following receipt of the April 2009 Complete Response Letter for Surfaxin, we reduced our workforce and restructured certain functions in research and development, primarily medical affairs. See, “– Results of Operations – General and Administrative Expenses.”

Contracted services include the cost of pre-clinical studies, clinical trial activities, certain components our manufacturing operations, quality control and analytical testing of our drug product, biological activity testing, consulting services, aerosol device design and engineering services, etc. Contracted services decreased over the three-year period primarily due to limiting our investment in our KL₄ pipeline programs to conserve financial resources following receipt of the May 2008 Approvable Letter.

Rents and utilities are associated with our leased manufacturing, laboratory and related facilities, including our manufacturing operations in Totowa, New Jersey. The decrease in rents and utilities over the three-year period is due to termination of leases for office and analytical laboratory space in Doylestown, Pennsylvania, and Mountain View, California, in mid-2008. The activities performed at these locations were consolidated in the fourth quarter of 2007 into our new analytical and development laboratory at corporate headquarters at, in Warrington, Pennsylvania.

Depreciation is associated with manufacturing and laboratory equipment, as well as leasehold improvements at our manufacturing operations in Totowa and our laboratories and related space at our headquarters in Warrington, Pennsylvania. The increase in depreciation from 2007 to 2008 is associated with investments made to complete the new analytical and development laboratory in Warrington, Pennsylvania, at the end of 2007. Approximately \$300,000 of depreciation in 2008 (and 2009) represents a full year of depreciation with respect to the new laboratory. The decline from 2008 to 2009 is due to our limiting purchases of equipment during 2008 and 2009 to conserve financial resources. In addition, certain older assets became fully depreciated in this period, resulting in a decrease in depreciation expense.

Raw materials and supplies consist of purchases of our active pharmaceutical ingredients for the manufacture of our KL₄ product candidates and supplies to support our manufacturing and laboratory operations, including component parts for the disposable dose delivery packets and patient interface system necessary to administer Aerosurf via our novel capillary aerosolization systems.

All other includes the cost of employee travel, insurances, shipping and taxes.

Research and Development Projects

A substantial portion of our cumulative losses to date, including approximately \$71.8 million in the three-year period ending December 31, 2009, relate to investments in our research and development activities. 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 individual projects in development are not reasonably estimable. With every phase of a development project, there are significant unknowns that may significantly impact cost projections and timelines. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty.

Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in “Item 1– Business – Government Regulation;” and in “Item 1A – Risk Factors– The regulatory approval process for our products is expensive and time-consuming and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products;” “– Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes;” “– Our ongoing clinical trials may be delayed, or fail, which will harm our business,” “– The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or the drug substances used to make our products, this could potentially cause us to delay development or clinical programs or, following approval, product launch, or cause us to experience shortages of products inventories;” as well as elsewhere in our Annual Report on Form 10-K.

Our lead development projects are initially focused on the management of RDS in premature infants and include Surfaxin, Surfaxin LS and Aerosurf. We believe that these neonatal programs have the potential to greatly improve the management of RDS and expand the current RDS market worldwide. All of these potential products are either in regulatory review or clinical or pre-clinical development and none are available for commercial sale. While we anticipate that we will be in a position to file a complete response with the FDA with respect to Surfaxin for the prevention of RDS in premature infants in the first quarter 2011, which could lead to potential approval of Surfaxin in 2011, there can be no assurance that we will be successful in securing such approval or that, if approved, we will be successful in commercializing Surfaxin and realizing a profit in the foreseeable future. We are preparing for clinical programs for Surfaxin LS and Aerosurf; however, our ability to move forward will depend upon the success of our efforts to secure appropriate strategic alliances and capital to fund these activities. Accordingly, we are unable to project when we might implement these programs, the pace of such implementation or the overall anticipated expense that we might incur.

The status of our lead projects and our other pipeline candidates, including the potential timing and milestones for each, is discussed in “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine.” See also, “Item 1 – Business – Business Strategy,” and “Item 1A – Risk Factors – We may not successfully develop and market our products, and even if we do, we may not become profitable,” “– We will require significant additional capital to continue our planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution.”

In addition to our lead products, we plan over time to develop our KL4 surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions in patient populations ranging from premature infants to adults. After we have completed Phase 2 proof-of-concept studies for each potential indication, if successful, we plan to assess the potential markets for these products and determine whether to seek strategic alliances or collaboration arrangements, or utilize other financial alternatives to fund their further development. At the present time, however, we continue to conserve our resources, predominantly by curtailing and pacing investments in these pipeline programs. See, “Item 1 – Business – Business Operations,” and “– Surfactant Replacement Therapy For Respiratory Medicine.”

Our ability to generate sufficient capital to support our product development activities and, if approved, commercialization plans, depends upon many factors, including the success of our efforts to secure one or more strategic alliances or other collaboration arrangements. We believe that our ability to successfully enter into meaningful strategic alliances will likely improve with advances, if any, that we are able to make in finalizing our development efforts and filing the Complete Response for Surfaxin, and in our Surfaxin LS and Aerosurf programs leading to initiation of clinical trials. There can be no assurance, however, that we will be able to secure strategic partners or collaborators to support and provide expert advice to guide our activities, that our research and development projects will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

Ultimately, if we do not successfully develop and gain marketing approval for our drug product candidates, in the United States or elsewhere, we will not be able to commercialize, or generate any revenues from the sale of, our products and the value of our company and our financial condition and results of operations will be substantially harmed.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs of executive management, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

General and administrative expenses for the years ended December 31, 2009, 2008, and 2007 were \$10.1 million, \$16.4 million, and \$13.7 million, respectively. General and administrative expenses included charges of \$2.2 million, \$3.1 million and \$3.6 million associated with stock-based employee compensation for the years ended December 31, 2009, 2008, and 2007, respectively.

Expenses for pre-launch commercial activities for the years ended December 31, 2009, and 2008 and 2007 were \$0.7, \$5.0 million, and \$2.2 million, respectively. A significant component of 2008 and 2007 general and administrative expenses is associated with pre-launch commercial activities to prepare for the potential approval and commercial launch of Surfaxin in May 2008. These activities began in the second half of 2007 and were accelerated in early 2008 up to receipt of the May 2008 Approvable Letter. Following receipt of the May 2008 Approvable Letter, we scaled back our commercial activities. Throughout the remainder of 2008 and into 2009, we made limited investments in our commercial capabilities in anticipation of the potential approval of Surfaxin in the United States. Following receipt of the April 2009 Complete Response Letter, we have reassessed our business strategy and have curtailed investment in commercial capabilities. We no longer plan to establish our own specialty pulmonary commercial organization to launch our KL₄ surfactant products in the United States and are now seeking to enter into strategic alliances to support our research and development programs and, if approved, to commercialize our products in all markets, including the United States. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded.

In addition, following receipt in April 2009 Complete Response Letter, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We incurred a one-time charge of \$0.6 million (\$0.4 million in general and administrative expenses and \$0.2 million in research and development expenses) in 2009 related to the workforce reduction. As of December 31, 2009, we had 77 full-time employees, the majority of which are devoted to research and development.

We believe our existing general and administrative resources, including legal, finance, business development, information technologies, human resources and general management capabilities, are sufficient to support our business operations for the foreseeable future. We may make additional investments in the future to enhance these capabilities as and when required to meet the needs of our business.

To sustain and perfect our potential competitive position, we expect to invest in maintaining our existing patent portfolio, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities, and when appropriate, patent extensions, new patents, new trademarks, and new regulatory exclusivity designations, when available. *See, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations."*

Change in Fair Value of Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815, as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued using the Black-Scholes pricing model at the date of initial issuance and each subsequent balance sheet date. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

The change in fair value of common stock warrant liability for the year ended December 31, 2009 resulted in income of \$0.4 million due primarily to a decrease in the Company's common stock share price during the period.

Other Income / (Expense)

Other income/(expense), net was (\$1.0) million, (\$0.7) million and (\$0.1) million for the years ended December 31, 2009, 2008 and 2007, respectively, as summarized in the chart below:

(Dollars in thousands)

	Year Ended December 31,		
	2009	2008	2007
Interest income	\$ 48	\$ 842	\$ 1,794
Interest expense	(1,096)	(1,614)	(1,906)
Other income / (expense)	5	60	54
Other income / (expense), net	<u>\$ (1,043)</u>	<u>\$ (712)</u>	<u>\$ (58)</u>

Interest income consists of interest earned on our cash and marketable securities. The decrease in interest income in 2009 and 2008 is due to a general decline in market interest rates and in our average cash and marketable securities balance.

Interest expense consists of interest accrued on the outstanding balance of our loan with Quintiles and under our equipment financing facilities. In addition, interest expense includes \$0.5 million, \$0.5 million and \$0.5 million for the years ended December 31, 2009, 2008 and 2007, respectively, associated with the amortization of deferred financing costs for warrants issued to Quintiles in October 2006 as consideration for restructuring our loan in 2006. The decrease in interest expense in 2009 and 2008 is due to a decline in the variable interest rate on our Quintiles loan, which is equal to the U.S. prime rate.

Other income/(expenses) primarily consists of proceeds from the sale of our Commonwealth of Pennsylvania research and development tax credits of \$5,000, \$0.1 million, and \$0.2 million for the years 2009, 2008 and 2007, respectively. The decrease in proceeds from the sale of these tax credits is due to more credits being available for sale in 2007 and 2008 as compared to 2009.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred substantial losses since inception due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our CEFFs, capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through a combination of these sources, as well as sales revenue from our product candidates, beginning with Surfaxin for the prevention of RDS, if approved.

Following receipt of the April 2009 Complete Response Letter for Surfaxin, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL₄ technology through strategic alliances or other collaboration arrangements. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors, which is included in our financial statements in this report, contains a notation related to our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through strategic and collaborative arrangements with potential partners and/or future debt and equity financings, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our December 31, 2009 financial statements do not include any adjustments relating to recoverability and classification of recorded

asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

Our future capital requirements depend upon many factors, including the success of our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL₄ surfactant products to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that we will be able to secure strategic partners to support our activities, that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements and continue our operations. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of December 31, 2009, we had cash and cash equivalents of \$15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of \$16.5 million (\$15.1 million net). Also, as of December 31, 2009, our \$10.5 million loan with Quintiles is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan; however, there can be no assurance that any such restructuring will occur. Currently, under our two CEFFs, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. However, as of March 5, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available because the market price of our common stock was below the minimum price required (\$1.15 and \$0.60, respectively) to utilize the facility. During 2009, we raised aggregate gross proceeds of \$22.0 million. In May 2009, we completed a registered direct public offering in resulting in gross proceeds of \$11.3 million (\$10.5 million net), and, throughout 2009, we raised an aggregate of \$10.7 million from 10 draw-downs under our CEFFs. See, “– Committed Equity Financing Facilities (CEFFs),” and “– Financings Pursuant to Common Stock Offerings.”

To meet our capital requirements, we continue to consider multiple strategic alternatives, including, but not limited to potential business alliances, commercial and development partnerships, additional financings and other similar opportunities, although there can be no assurance that we will take any further specific actions or enter into any transactions. Until such time as we secure the necessary capital, we plan to continue conserving our financial resources, predominantly by limiting investments in our pipeline programs. See, “Item 1A – Risk Factors – We will require significant additional capital to continue our planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution,” and “– The terms of our indebtedness may impair our ability to conduct our business,” “– Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our CEFFs, stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.”

Cash Flows

We had cash, cash equivalents and marketable securities of \$15.7 million, \$24.8 million and \$53.0 million as of December 31, 2009, 2008 and 2007, respectively. The decrease of \$9.1 million in 2009 is primarily due to \$30.0 million used in operating activities, capital expenditures and principal payments on equipment loans, partially offset by proceeds of \$10.4 million from financings under our CEFFs and \$10.5 million from our May 2009 Registered Direct Offering. See, “– Committed Equity Financing Facilities (CEFFs),” and “– Financings Pursuant to Common Stock Offerings.”

Cash Flows Used in Operating Activities

Cash flows used in operating activities were \$27.4 million, \$31.8 million and \$29.4 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Our cash flows used in operating activities are a result of our net operating losses adjusted for non-cash items associated with stock-based compensation, fair value adjustment of common stock warrants, depreciation and changes in our accounts payable and accrued liabilities. *See*, “– Results of Operations.” Cash flows from operating activities in 2008 also include \$4.5 million received from Chrysalis to support development of our capillary aerosolization technology.

Cash Flows From / (Used in) Investing Activities

Cash flows from / (used in) investing activities include capital expenditures of \$0.1 million, \$0.6 million and \$3.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. Capital expenditures were primarily for laboratory and manufacturing equipment to support analytical, quality, manufacturing and development activities. In 2007, we completed construction of a new analytical and development laboratory in our headquarters in Warrington, Pennsylvania, for a total cost of approximately \$3.0 million and consolidated at this location the analytical, quality and development activities previously conducted at locations in Doylestown, Pennsylvania, and Mountain View, California. The new laboratory expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to exploit our internal professional expertise across a broad range of projects, improving both operational efficiency and financial economics. The leases for our Doylestown, Pennsylvania, and Mountain View, California, locations either expired or terminated in 2008. *See*, “– Contractual Obligations.”

Cash flows from / (used in) investing activities also include cash used to purchase short-term marketable securities and cash received from the sale and/or maturity of short-term marketable securities. When assessing our cash position and managing our liquidity and capital resources, we do not consider cash flows between cash and marketable securities to be meaningful. Cash used to purchase marketable securities is subject to an investment policy that is approved by the Board of Directors and provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs. As of December 31, 2009, the company did not have any available-for-sale marketable securities.

Cash Flows from Financing Activities

Cash flows from financing activities were \$18.3 million, \$4.2 million and \$59.7 million for the years ended December 31, 2009, 2008 and 2007, respectively, as summarized in the chart below:

(In millions)

	Year Ended December 31,		
	2009	2008	2007
Financings under CEFFs	\$ 10.3	\$ 6.3	\$ 7.0
Financings pursuant to common stock offerings	10.5	–	51.7
Proceeds from equipment financing facilities	–	0.9	2.9
Debt service payments	(2.5)	(3.0)	(1.9)
Cash flows from financing activities, net	<u>\$ 18.3</u>	<u>\$ 4.2</u>	<u>\$ 59.7</u>

The following sections provide a more detailed discussion of our cash flows from financing activities.

Committed Equity Financing Facilities (CEFFs)

We have entered into four Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under which Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allow us, at our discretion, to raise capital at the time and in amounts deemed suitable to us, to support our business plans. We are not obligated to utilize any of the funds available under the CEFFs. Each CEFF is available for a period of two or three years from inception. Should we choose to utilize any of the CEFFs, our ability to access the funds available under the CEFFs is subject to certain conditions, including stock price and volume limitations.

As of December 31, 2009, we had two CEFFs available for future financings as follows: the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). A third CEFF entered in April 2006 expired on May 12, 2009 and is no longer available. The following table sets forth an overview of the “draw down” requirements and availability under each CEFF:

(in millions, except per share data and trading days)

CEFF	Expiration	Minimum Price to Initiate Draw Down ⁽¹⁾	Minimum VWAP for Daily Pricing ⁽²⁾	# of Trading Days In Each Draw Down ⁽²⁾	Amount per Contract		Potential Availability at December 31, 2009	
					Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008	June 18, 2011	\$1.15	90% of the closing market price on the day preceding the first day of draw down	8	19.3	\$60.0	12.8	\$51.8
Dec. 2008	Feb. 6, 2011	\$0.60		6	15.0	\$25.0	7.1	\$17.7

- (1) To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day of the draw down period must be at least equal to the minimum price set forth above.
- (2) If on any trading day, the daily volume-weighted average of our common stock (VWAP) is less than the minimum VWAP set forth above, no shares are purchased on that trading day and the aggregate amount that we originally designated for the overall draw down is reduced for each such day by 1/8th in the case of the December 2008 CEFF, and 1/6th in the case of the May 2008 CEFF, respectively. Unless we and Kingsbridge agree 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.

Each draw down is limited in amount as follows:

- May 2008 CEFF – the lesser of 3.0 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or \$10 million; and
- December 2008 CEFF – the lesser of 1.5 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or \$3 million.

The purchase price of shares sold to Kingsbridge under the CEFFs is at a discount to the VWAP (as defined in the applicable agreement) for each of the trading days following our initiation of a “draw down” under the CEFF, as follows:

<u>Daily VWAP</u>	<u>% of VWAP</u>	<u>Applicable Discount</u>
May 2008 CEFF		
Greater than \$7.25 per share	94%	6%
Less than or equal to \$7.25 but greater than \$3.85 per share	92%	8%
Less than or equal to \$3.85 but greater than \$1.75 per share	90%	10%
Less than or equal to \$1.75 but greater than or equal to \$1.15 per share	88%	12%
December 2008 CEFF		
Greater than \$7.25 per share	94%	6%
Less than or equal to \$7.25 but greater than \$3.85 per share	92%	8%
Less than or equal to \$3.85 but greater than \$1.75 per share	90%	10%
Less than or equal to \$1.75 but greater than or equal to \$1.10 per share	88%	12%
Less than or equal to \$1.10 but greater than or equal to \$0.60	85%	15%

In addition, Kingsbridge may terminate the CEFFs under certain circumstances, including if a material adverse event relating to our business continues for 10 trading days after notice of the material adverse event.

In connection with the December 2008 CEFF, we issued a warrant to Kingsbridge on December 22, 2008 to purchase up to 675,000 shares of our common stock at an exercise price of \$1.5132 per share. The warrant expires

in May 2014 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$1.0 million. As of December 31, 2009, this warrant had not been exercised.

In connection with the May 2008 CEFF, we issued a warrant to Kingsbridge on May 22, 2008 to purchase up to 825,000 shares of our common stock at an exercise price of \$2.506 per share. The warrant expires in November 2013 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.1 million. As of December 31, 2009, this warrant had not been exercised.

In connection with the 2006 CEFF, we issued a Class C Investor Warrant to Kingsbridge on April 17, 2006 to purchase up to 490,000 shares of our common stock at an exercise price equal to \$5.6186 per share. The warrant expires in October 2011 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.8 million. As of December 31, 2009, this Class C Investor Warrant had not been exercised.

In connection with a CEFF that we entered in 2004, 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 expired unexercised in January 2010.

CEFF Financings

The financings that we completed under the December 2008 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
April 8, 2009	806	\$ 1,000	\$ 1.24
May 7, 2009	1,273	1,000	0.79
September 23, 2009	1,793	1,583	0.88
October 13, 2009	1,909	1,800	0.94
October 21, 2009	2,101	1,900	0.90

The financings that we completed under the May 2008 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
July 11, 2008	1,105	\$ 1,563	\$ 1.41
July 31, 2008	992	1,500	1.51
October 17, 2008	914	1,313	1.44
November 20, 2008	221	250	1.13
January 2, 2009	479	500	1.04
January 16, 2009	419	438	1.04
February 18, 2009	857	1,000	1.17
March 31, 2009	1,015	1,094	1.08
October 13, 2009	559	606	1.09

The financings that we completed under the now expired 2006 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
May 29, 2006	1,079	\$ 2,188	\$ 2.03
October 11, 2006	1,205	2,300	1.91
November 10, 2006	1,372	3,000	2.19
February 22, 2007	943	2,000	2.12
October 12, 2007	1,909	5,000	2.62
September 9, 2008	676	1,250	1.85

Financings Pursuant to Common Stock Offerings

Historically, we have funded, and expect to continue to fund, our business operations through various sources, including financings pursuant to common stock offerings.

2008 Universal Shelf

In June 2008, we filed a universal shelf registration statement on Form S-3 (No. 333-151654) (“2008 Universal Shelf”) with the SEC for the proposed offering from time to time of up to \$150 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at that time.

In February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of \$0.60 per unit, resulting in gross and net proceeds to us of \$16.5 million and approximately \$15.1 million, respectively. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of \$0.85, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis.

In May 2009, we completed a registered direct offering of 14,000,000 shares of our common stock and warrants to purchase 7,000,000 shares of our common stock, sold as units to select institutional investors, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at an offering price of \$0.81 per unit, resulting in gross and net proceeds to us of \$11.3 million and \$10.5 million, respectively. The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of \$1.15, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis.

As of December 31, 2009 and March 1, 2010, respectively, up to \$138.7 million and \$122.2 million of our securities are potentially available for issuance pursuant to the 2008 Universal Shelf.

2005 Universal Shelf

In October 2005, we filed a universal shelf registration statement on Form S-3 (File No. 333-128929) (2005 Universal Shelf) with the SEC for the proposed offering, from time to time, of up to \$100 million of our debt or equity securities.

In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors. The shares were priced at \$2.50 per share resulting in gross and net proceeds to us of \$25.0 million and \$23.6 million, respectively.

In April 2007, we completed 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 and net proceeds to us of \$30.2 million and \$28.1 million, respectively.

The October 2005 universal shelf registration statement expired in December 2008 and is no longer available.

Debt

Historically, we have funded, and expect to continue to fund, our business operations through various sources, including debt arrangements such as credit facilities and equipment financing facilities.

Loan with Quintiles

Quintiles extended to us a secured, revolving credit facility, which we restructured in October 2006. The outstanding principal balance of the loan, \$8.5 million, is due and payable on April 30, 2010, together with all unpaid interest accrued since July 1, 2006. Since October 2006, interest is calculated at the prime rate, compounded annually. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. In addition, our obligations to Quintiles under the loan agreement are secured by a security interest in substantially all of our assets, subject to limited exceptions set forth in the related security agreement.

Also in October 2006, in consideration of Quintiles's agreement to restructure the loan, we entered into a Warrant Agreement with Quintiles, pursuant to which Quintiles has the right to purchase 1.5 million shares of our common stock at an exercise price of \$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 Quintiles 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.

As of December 31, 2009, the outstanding balance under the loan was \$10.5 million (\$8.5 million principal and \$2.0 million accrued interest) and was classified as a current liability on the Consolidated Balance Sheets as of such date.

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the Quintiles loan of \$0.3 million, \$0.5 million and \$0.7 million, respectively. The decrease in interest expense in 2009 and 2008 is due to declines in the prime rate during 2008 ranging from 7.25% to 3.25%. During 2009, the prime rate remained at 3.25%. In addition, for the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to Quintiles in October 2006 of \$0.5 million, \$0.5 million and \$0.5 million, respectively.

Equipment Financing Facilities

Historically, we have funded our purchases of capital expenditures through the use of equipment financing facilities, although we currently do not have a facility available. The outstanding principal balance of these facilities as of December 31, 2009 and 2008 was as follows:

<i>(in thousands)</i>	2009	2008
GE Business Financial Services, Inc.		
Short-term	\$ 538	\$ 2,385
Long-term	65	664
Total	603	3,049
Pennsylvania Machinery and Equipment Loan		
Short-term	59	57
Long-term	363	428
Total	422	485
Total Short-term	597	2,442
Total Long-term	428	1,092
Total	\$ 1,025	\$ 3,534

GE Business Financial Services Inc.

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide us a \$12.5 million facility (Facility) to fund our capital programs. The right to draw under this Facility expired on November 30, 2008. Over the term of the Facility, we received \$7.2 million, \$4.0 million of which was applied to prepayment of a prior facility and \$2.3 million of which was associated with construction and equipment for the analytical and development laboratory that we built in our Warrington, Pennsylvania headquarters in 2007.

Proceeds received under the Facility were \$0.0 million, \$0.4 million and \$6.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. Advances under the Facility to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our prior facility is amortized over a period of 27 months. Interest on each advance accrues at a fixed rate per annum equal to one-month LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances are 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%.

Principal payments under the Facility were \$2.4 million, \$3.0 million and \$1.2 million for the years ended December 31, 2009, 2008 and 2007, respectively. Interest expense under the Facility was \$0.2 million, \$0.5 million and \$0.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. The remaining outstanding loan balance under the Facility was \$0.6 million as of December 31, 2009, which will be paid over the next 21 months, with the final payment in September 2011.

Our obligations under the Facility are secured by a security interest in (i) the financed property and equipment, and (ii) all of our intellectual property (Supplemental Collateral), subject to limited exceptions set forth in the Loan Agreement. The Supplemental Collateral will be released on the earlier to occur of (a) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (b) 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, GE and Quintiles entered into an Intercreditor Agreement under which GE 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 Quintiles (as discussed above).

Pennsylvania – Department of Community and Economic Development – Machinery and Equipment Loan Fund

We entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department) in September 2008, pursuant to which the Department made a loan to us from the Machinery and Equipment Loan Fund in the amount of \$500,000 (MELF Loan) to fund

the purchase and installation of new machinery and equipment and the upgrade of existing machinery and equipment at our analytical and development laboratory in Warrington, Pennsylvania. Principal and interest on the MELF Loan is payable in equal monthly installments over a period of seven years. Interest on the principal amount accrues at a fixed rate of five percent (5.0%) per annum. We may prepay the MELF Loan at any time without penalty.

In addition to customary terms and conditions, the MELF Agreement provides that we must meet certain criteria regarding retention and creation of new jobs within a three-year period. In the event that we fail to comply with this requirement, the interest rate on the Promissory Note, except in limited circumstances, will be adjusted to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2009, 2008 or 2007, or for the periods then ended.

Contractual Obligations

Payments due under contractual debt obligations at December 31, 2009, including principal and interest, are as follows:

(in thousands)

	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>There- after</u>	<u>Total</u>
Loan payable ⁽¹⁾	\$ 10,573	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 10,573
Equipment loan obligations ⁽¹⁾	722	152	85	85	85	70	1,199
Operating lease obligations	1,127	1,146	1,166	320	150	—	3,909
CEO severance obligations	<u>1,211</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,211</u>
Total	<u>\$ 13,633</u>	<u>\$ 1,298</u>	<u>\$ 1,251</u>	<u>\$ 405</u>	<u>\$ 235</u>	<u>\$ 70</u>	<u>\$ 16,892</u>

⁽¹⁾ See, “— Liquidity and Capital Resources - Debt.” For the purposes of this table, we have assumed that the Quintiles Loan will accrue interest through maturity at an average rate that is equal to the current prime rate of 3.25%.

Operating Lease Agreements

Our operating leases consist primarily of facility leases for our operations in Pennsylvania and New Jersey. 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, analytical technical services, research and development, 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 approximately 21,000 square feet of space for our manufacturing facility in Totowa, New Jersey, at an annual rent of \$150,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires in December 2014, subject to the landlord’s right, upon two years’ prior notice, to terminate the lease early. This early termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, depending upon the timing of the notice, if we satisfy certain financial conditions, the landlord would be obligated to make early termination payments to us. At the present time, we understand that the master tenant continues to be active in the premises. The total aggregate payments over the term of the lease are \$1.4 million. In connection with our manufacturing operations in Totowa, New Jersey, we

have 15 employees subject to a collective bargaining arrangement which expires on December 3, 2010. *See*, “Item 1 – Business – Business Operations – Manufacturing and Distribution,” and “Item 2 – Properties.”

Our lease for 5,600 square feet of office and analytical laboratory space in Doylestown, Pennsylvania was terminated effective July 31, 2008 and all activities at this location have been consolidated into our laboratory space in Warrington, Pennsylvania. Our lease for 16,800 square feet of office and laboratory space at our facility in Mountain View, California, expired without renewal or extension on June 30, 2008. In December 2007, we consolidated these activities into our laboratory space in Warrington, Pennsylvania.

Rent expense under all leases for the years ended December 31, 2009, 2008, and 2007 was \$1.1 million, \$1.2 million and \$1.5 million respectively.

Former CEO Commitment

Effective August 13, 2009, Dr. Robert J. Capetola resigned his positions as our President and Chief Executive Officer and as a member of our Board. The Board elected Mr. W. Thomas Amick, Chairman of the Board, to serve as Chief Executive Officer on an interim basis. We entered into a separation agreement and general release (Separation Agreement) with Dr. Capetola providing for (i) an upfront severance payment of \$250,000, and (ii) periodic payments in an amount equal to his base salary (calculated at a rate of \$490,000 per annum), in accordance with our payroll practices and less required withholdings. The periodic payments will end the earlier of (x) May 3, 2010 or (y) the date, if ever, that a Corporate Transaction (as defined below) occurs. In addition, Dr. Capetola will be entitled to (A) continuation of medical benefits and insurance coverage for a period of 24 or 27 months, depending upon circumstances, and (B) accelerated vesting of all outstanding restricted shares and options, which shall remain exercisable to the end of their stated terms.

The Separation Agreement provides further that, upon the occurrence of a Corporate Transaction prior to May 4, 2010, Dr. Capetola will receive a payment of up to \$1,580,000 (the “Additional Severance”) or, if any such Corporate Transaction also constitutes a Change of Control (as such term is defined in the Separation Agreement), a payment of up to \$1,777,500; provided, however, that, in each case, any such payment will be reduced by the sum of the amounts described in clauses (i) and (ii) of this paragraph that theretofore have been paid. A “Corporate Transaction” is defined in the Separation Agreement as (1) one or more corporate partnering or strategic alliance transactions, Business Combinations or public or private financings that (A) are completed during the Severance Period (as defined in the Separation Agreement) and (B) result in cash proceeds (net of transaction costs) to the Company of at least \$20 million received during the Severance Period or within 90 calendar days thereafter, or (2) an acquisition of the Company, by business combination or other similar transaction, that occurs during the Severance Period and the consideration paid to stockholders of the Company, in cash or securities, is at least \$20 million. For this purpose, net proceeds will be calculated without taking into account any amounts received by the Company as reimbursement for costs of development and research activities to be performed in connection with any such transaction.

Since August 13, 2009, we have raised approximately \$5.89 million in gross proceeds utilizing our CEFFs (*see*, “– Committed Equity Financing Facilities (CEFFs)”). In addition, on February 23, 2010, we completed a public offering that resulted in net proceeds to us of approximately \$15.1 million (*see*, “– Financings Pursuant to Common Stock Offerings.”). As the receipt from financings of more than \$20 million qualifies as a Corporate Transaction, our obligation under the Separation Agreement to make payment to Dr. Capetola of the Additional Severance has matured. Therefore, in accordance with the Separation Agreement, on March 5, 2010, we issued a payment to Dr. Capetola in the amount of approximately \$1.06 million (less withholding), representing his Additional Severance payment, reduced by the payments previously made to him under the Severance Agreement, which total approximately \$0.52 million. Our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due at this time.

Future Milestone Commitment

In addition to the contractual obligations above, we have certain milestone and royalty payment obligations to Johnson & Johnson related to our product licenses. To date, of the \$2,500,000 aggregate potential milestone payments, we have paid \$450,000 for milestones that have been achieved.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See, Index to Consolidated Financial Statements on Page F-1 attached hereto.

ITEM 9A. 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.

In connection with the preparation of this Amendment No. 2, our Chief Executive Officer and our Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2009. In making this evaluation, they considered the material weakness related to the initial classification and subsequent accounting for warrants discussed below. Solely as a result of the material weakness, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2009.

(b) Management's Report on our Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

In connection with this Amendment No. 2, management, including our Chief Executive Officer and Chief Financial Officer, reassessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. This evaluation identified a material weakness in our internal control regarding our process and procedures related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments. This material weakness in our internal controls resulted in the restatement of our 2009 financial statements. As a result, management has revised its assessment to conclude that our internal control over financial reporting was not effective as of December 31, 2009, based on the COSO criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

(c) Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc. and Subsidiary

We have audited Discovery Laboratories, Inc. and subsidiary's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Discovery Laboratories, Inc. and subsidiary's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on our Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our report dated March 10, 2010, we expressed an unqualified opinion that the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria. Management has subsequently determined that a deficiency in controls relating to the accounting for registered warrants existed as of the previous assessment date, and has further concluded that such deficiency represented a material weakness as of December 31, 2009. As a result, management has revised its assessment, as presented in the accompanying Management's Report on Internal Control over Financial Reporting, to conclude that the Company's internal control over financial reporting was not effective as of December 31, 2009. Accordingly, our present opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2009, as expressed herein, is different from that expressed in our previous report.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified a material weakness in internal controls over the classification of and subsequent accounting for registered warrants. Specifically, the process and procedures for the classification and subsequent accounting of registered warrants as liabilities or equity instruments were not effective. This material weakness in internal controls over registered warrants resulted in the restatement of the 2009 financial statements. We also have audited, in accordance with the standards of the Public

Company Accounting Oversight Board (United States), the consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2009 consolidated financial statements, and this report does not affect our report dated March 10, 2010, except for Note 2, Note 4 and Note 5, as to which the date is November 12, 2010, on those consolidated financial statements (as restated).

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 10, 2010, except for
the effects of the material weakness described in the
sixth paragraph above, as to which the date is November 12, 2010

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

The consolidated financial statements required to be filed in this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements on page F-1 hereof.

Exhibits are listed on the Index to Exhibits at the end of this Annual Report on Form 10-K. The exhibits required to be filed pursuant to Item 601 of Regulation S-K, which are listed on the Index in response to this Item, are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: November 12, 2010

By: /s/ W. Thomas Amick
W. Thomas Amick, Chairman of the Board
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Name & Title</u>	<u>Date</u>
/s/ W. Thomas Amick	W. Thomas Amick Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	November 12, 2010
/s/ John G. Cooper	John G. Cooper President and Chief Financial Officer	November 12, 2010
/s/ John Tattory	John Tattory Vice President, Finance, and Controller (Principal Accounting Officer)	November 12, 2010
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	November 12, 2010
/s/ Max E. Link	Max E. Link, Ph.D. Director	November 12, 2010
/s/ Herbert H. McDade, Jr.	Herbert H. McDade, Jr. Director	November 12, 2010
/s/ Bruce A. Peacock	Bruce A. Peacock Director	November 12, 2010
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	November 12, 2010

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K/A.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), dated December 9, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 9, 2009.
3.2	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.
3.3	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009
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 for the quarter ended September 30, 2004, as filed with the SEC on November 9, 2004.
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	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.
4.7	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.
4.8	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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.9	Warrant Agreement dated May 22, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on May 28, 2008.
4.10	Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
4.11	Form of Stock Purchase Warrant issued in May 2009	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 8, 2009.
4.12	Form of Stock Purchase Warrant issued in February 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 18, 2010.
4.13	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.1+	Sublicense Agreement, dated as of October 28, 1996, between Johnson & Johnson, Ortho Pharmaceutical Corporation and Acute Therapeutics, Inc.	Incorporated by reference to Exhibit 10.6 to Discovery's Registration Statement on Form SB-2/A, as filed with the SEC on April 18, 1997 (File No. 333-19375).
10.2	Registration Rights Agreement, dated June 16, 1998, among Discovery, Johnson & Johnson Development Corporation and The Scripps Research Institute.	Incorporated by reference to Exhibit 10.28 to Discovery's Annual Report on Form 10-KSB for the year ended December 31, 1998, as filed with the SEC on April 9, 1999.
10.3*	Restated 1993 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.4*	1995 Stock Option Plan of Discovery.	Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).
10.5*	Amended and Restated 1998 Stock Incentive Plan of Discovery (amended as of May 13, 2005).	Incorporated by reference to Exhibit 4.1 to Discovery's Registration Statement on Form S-8, as filed with the SEC on August 23, 2005 (File No. 333-116268).
10.6*	Form of Notice of Grant of Stock Option under the 1998 Stock Incentive Plan.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-QSB for the quarter ended September 30, 1999, as filed with the SEC on November 17, 1999.
10.7*	Discovery's 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.8*	Form of 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.
10.9*	Form of Stock Issuance Agreement, dated as of October 30, 2007, between the Discovery and the Grantees	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 5, 2007.
10.10+	Amended and Restated Sublicense and Collaboration Agreement made as of December 3, 2004, between Discovery and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.28 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.11+	Amended and Restated Supply Agreement, dated as of December 3, 2004, by and between Discovery and Laboratorios del Dr. Esteve, S.A.	Incorporated by reference to Exhibit 10.29 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC on March 16, 2005.
10.12	Assignment of Lease and Termination and Option Agreement, dated as of December 30, 2005, between Laureate Pharma, Inc. and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2005, as filed with the SEC on March 16, 2006.
10.13	Common Stock Purchase Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
10.14	Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
10.15*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert J. Capetola, Ph.D.	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.16*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert J. Capetola and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008
10.17*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and John G. Cooper.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.18*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between John G. Cooper and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.19*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and David L. Lopez, Esq., CPA	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.20*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between David L. Lopez and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 3, 2008.
10.21*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert Segal, M.D.	Incorporated by reference to Exhibit 10.4 to Discovery's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC on May 10, 2006.
10.22*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert Segal, M.D., F.A.C.P., and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 15, 2008.
10.23*	Amendment dated December 12, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert Segal, M.D., F.A.C.P., and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 18, 2008.
10.24*	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Charles Katzer.	Incorporated by reference to Exhibit 10.31 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the SEC on March 16, 2007.
10.25*	Amendment to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Charles F. Katzer 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 15, 2008.
10.26*	Amendment dated December 12, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Charles F. Katzer and Discovery Laboratories, Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 18, 2008.
10.27	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Discovery Laboratories, Inc.	Incorporated by reference to Exhibits 10.1 and 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.28	Credit and Security Agreement, dated as of May 21, 2007, by and between Discovery and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services, Inc.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 24, 2007.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.29	First Amendment to Credit and Security Agreement (the “Amendment”) dated May 30, 2008, between the Company and GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services, Inc.)	Incorporated by reference to Exhibit 10.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on June 2, 2008.
10.30 +	Amended and Restate License Agreement by and between Discovery and Philip Morris USA Inc., d/b/a/ Chrystalis Technologies, dated March 28, 2008	Incorporated by reference to Exhibit 10.4 to Discovery’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.31 +	License Agreement by and between and Philip Morris Products S.A., dated March 28, 2008	Incorporated by reference to Exhibit 10.5 to Discovery’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008.
10.32	Common Stock Purchase Agreement, dated as of May 22, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on May 27, 2008.
10.33	Registration Rights Agreement, dated as of December 12, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.2 to Discovery’s Current Report on Form 8-K, as filed with the SEC on May 27, 2008.
10.34	Common Stock Purchase Agreement, dated December 12, 2008, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
10.35	Registration Rights Agreement, dated as of December 12, 2008, by and between Kingsbridge Capital and Discovery	Incorporated by reference to Exhibit 10.2 to Discovery’s Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
10.36*	Agreement, dated as of August 13, 2009, by and between Discovery and W. Thomas Amick Regarding Service as Chief Executive Officer on a Part-Time, Interim Basis	Incorporated by reference to Exhibit 10.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
10.37*	Separation of Employment Agreement and General Release, dated as of August 13, 2009, by and between Discovery and Robert J. Capetola	Incorporated by reference to Exhibit 10.2 to Discovery’s Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
10.38	Payment Agreement and Loan Amendment (amending the Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006) dated April 27, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 1.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.39	Third Amended Promissory Note dated April 27, 2010 (amending and restating the Second Amended Promissory Note dated as of October 25, 2006), payable to PharmaBio	Incorporated by reference to Exhibit 1.2 to Discovery’s Current Report on Form 8-K, as filed with the SEC on April 28, 2010.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.40	Securities Purchase Agreement dated April 27, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 1.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
21.1	Subsidiaries of Discovery.	Incorporated by reference to Exhibit 21.1 to Discovery's Annual Report on Form 10-KSB for the year ended December 31, 1997, as filed with the SEC on March 31, 1998.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.	Incorporated by reference to Exhibit 23.1 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 10, 2010.
23.2	Consent of Ernst & Young LLP, independent registered public accounting firm.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.1 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 10, 2010.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.2 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 10, 2010.
31.3	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.3 to Discovery's Annual Report on Form 10-K/A for the year ended December 31, 2009, as filed with the SEC on April 30, 2010.
31.4	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.4 to Discovery's Annual Report on Form 10-K/A for the year ended December 31, 2009, as filed with the SEC on April 30, 2010.
31.5	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.6	Certification of Chief Financial 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.	Incorporated by reference to Exhibit 32.1 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 10, 2010.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
32.2	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.	Incorporated by reference to Exhibit 31.4 to Discovery's Annual Report on Form 10-K/A for the year ended December 31, 2009, as filed with the SEC on April 30, 2010.
32.3	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.

+ Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report pursuant to Item 15(b) of Form 10-K.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary (the "Company") as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. and subsidiary at December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 3, the Company has incurred recurring operating losses and has generated negative cash flows from operations since inception and expects such results to continue for the foreseeable future. In addition, there is uncertainty as to the Company's ability to raise additional capital sufficient to meet its obligations on a timely basis. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 3. The December 31, 2009 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, the 2009 consolidated financial statements have been restated to correct an error related to the accounting for registered warrants.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2010, except for the effects of the material weakness described in the sixth paragraph of that report, as to which the date is November 12, 2010, expressed an adverse opinion thereon.

/s/ Ernst & Young LLP

Philadelphia, PA
March 10, 2010, except for Note 2, Note 4, and
Note 5, as to which the date is November 12, 2010

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
DRAFT: FOR DISCUSSION PURPOSES ONLY

Consolidated Balance Sheets

(In thousands, except per share data)

	December 31, 2009 (As Restated)	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 15,741	\$ 22,744
Available-for-sale marketable securities	—	2,048
Prepaid expenses and other current assets	233	625
Total current assets	15,974	25,417
Property and equipment, net	4,668	5,965
Restricted cash	400	600
Other assets	361	907
Total assets	<u>\$ 21,403</u>	<u>\$ 32,889</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,294	\$ 2,111
Accrued expenses	3,446	5,313
Common stock warrant liability	3,191	—
Loan payable, including accrued interest	10,461	—
Equipment loan, current portion	597	2,442
Total current liabilities	18,989	9,866
Loan payable, including accrued interest	—	10,128
Equipment loan, non-current portion	428	1,092
Other liabilities	690	870
Total liabilities	20,107	21,956
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 380,000 and 180,000 shares authorized; 126,689 and 101,588 shares issued, 126,376 and 101,275 shares outstanding	127	102
Additional paid-in capital	361,503	341,293
Accumulated deficit	(357,280)	(327,409)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Accumulated other comprehensive income	—	1
Total stockholders' equity	1,296	10,933
Total liabilities & stockholders' equity	<u>\$ 21,403</u>	<u>\$ 32,889</u>

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Operations

(In thousands, except per share data)

	Year Ended December 31,		
	2009	2008	2007
	(As Restated)		
Revenue from collaborative arrangement and grants:	\$ —	\$ 4,600	\$ —
Expenses:			
Research & development	19,077	26,566	26,200
General & administrative	10,120	16,428	13,747
Total expenses	29,197	42,994	39,947
Operating loss	(29,197)	(38,394)	(39,947)
Change in fair value of common stock warrant liability	369	-	-
Other income / (expense):			
Interest and other income	39	902	2,029
Interest and other expense	(1,082)	(1,614)	(2,087)
Other income / (expense), net	(1,043)	(712)	(58)
Net loss	<u>\$ (29,871)</u>	<u>\$ (39,106)</u>	<u>\$ (40,005)</u>
Net loss per common share - basic and diluted	\$ (0.26)	\$ (0.40)	\$ (0.49)
Weighted average number of common shares outstanding - basic and diluted	115,200	98,116	81,731

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Changes in Stockholders' Equity For Years Ended December 31, 2009, 2008 and 2007

(In thousands)

	Common Stock Shares	Amount	Additional Paid-in Capital (As Restated)	Unearned Portion of Compensatory Stock Options	Accumulated Deficit (As Restated)	Treasury Stock Shares	Amount	Accumulated Other Com- prehensive Income/(Loss)	Total (As Restated)
Balance – January 1, 2007	69,871	\$ 70	\$ 265,604	\$ –	\$ (248,298)	(313)	\$ (3,054)	\$ –	\$ 14,322
Comprehensive loss:									
Net loss	–	–	–	–	–	–	–	–	(40,005)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	42	42
Total comprehensive loss	–	–	–	–	–	–	–	–	(39,963)
Issuance of common stock, stock option exercises	62	–	106	–	–	–	–	–	106
Issuance of common stock, 401(k) employer match	118	–	294	–	–	–	–	–	294
Issuance of common stock, April 2007 financing	14,050	14	28,131	–	–	–	–	–	28,145
Issuance of common stock, December 2007 financing	10,000	10	23,550	–	–	–	–	–	23,560
Issuance of common stock, CEFF financings	2,852	3	6,997	–	–	–	–	–	7,000
Stock-based compensation expense	–	–	5,317	–	–	–	–	–	5,317
Balance – December 31, 2007	96,953	\$ 97	\$ 329,999	\$ –	\$ (288,303)	(313)	\$ (3,054)	\$ 42	\$ 38,781
Comprehensive loss:									
Net loss	–	–	–	–	–	–	–	–	(39,106)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	(41)	(41)
Total comprehensive loss	–	–	–	–	–	–	–	–	(39,147)
Issuance of common stock, stock option exercises	18	–	21	–	–	–	–	–	21
Issuance of common stock, 401(k) employer match	231	–	380	–	–	–	–	–	380
Issuance of common stock, CEFF financings	4,387	5	6,266	–	–	–	–	–	6,271
Stock-based compensation expense	–	–	4,627	–	–	–	–	–	4,627
Balance – December 31, 2008	101,589	\$ 102	\$ 341,293	\$ –	\$ (327,409)	(313)	\$ (3,054)	\$ 1	\$ 10,933
Comprehensive loss:									
Net loss	–	–	–	–	–	–	–	–	(29,871)
Other comprehensive loss – unrealized gains on investments	–	–	–	–	–	–	–	(1)	(1)
Total comprehensive loss	–	–	–	–	–	–	–	–	(29,872)
Issuance of common stock, restricted stock awards	21	–	–	–	–	–	–	–	–
Issuance of common stock, 401(k) employer match	347	–	290	–	–	–	–	–	290
Issuance of common stock, May 2009 financing	14,000	14	6,891	–	–	–	–	–	6,905
Issuance of common stock, CEFF financings	10,732	11	10,346	–	–	–	–	–	10,357
Stock-based compensation expense	–	–	2,683	–	–	–	–	–	2,683
Balance – December 31, 2009	126,689	\$ 127	\$ 361,503	\$ –	\$ (357,280)	(313)	\$ (3,054)	\$ –	\$ 1,296

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2009	2008	2007
	(As Restated)		
Cash flow from operating activities:			
Net loss	\$ (29,871)	\$ (39,106)	\$ (40,005)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,992	2,215	2,062
Stock-based compensation and 401(k) match	2,973	5,007	5,613
Fair value adjustment of common stock warrants	(369)		
Loss on disposal of property and equipment	—	110	18
Changes in:			
Prepaid expenses and other current assets	392	(56)	(89)
Accounts payable	(817)	1,353	(871)
Accrued expenses	(1,867)	(1,773)	2,762
Other assets	(1)	3	35
Other liabilities and accrued interest on loan payable	153	495	1,080
Net cash used in operating activities	(27,415)	(31,752)	(29,395)
Cash flow from investing activities:			
Purchase of property and equipment	(147)	(632)	(3,765)
Restricted cash	200	-	-
Purchase of marketable securities	—	(25,765)	(38,355)
Proceeds from sale or maturity of marketable securities	2,047	39,754	22,319
Net cash provided by / (used in) investing activities	2,100	13,357	(19,801)
Cash flow from financing activities:			
Proceeds from issuance of securities, net of expenses	20,820	6,292	58,809
Proceeds from equipment loans	—	896	2,862
Principal payments under equipment loan obligations	(2,508)	(2,978)	(1,948)
Net cash provided by financing activities	18,312	4,210	59,723
<u>Net (decrease) / increase in cash and cash equivalents</u>	(7,003)	(14,185)	10,527
Cash and cash equivalents – beginning of year	22,744	36,929	26,402
<u>Cash and cash equivalents – end of year</u>	<u>\$ 15,741</u>	<u>\$ 22,744</u>	<u>\$ 36,929</u>
Supplementary disclosure of cash flows information:			
Interest paid	\$ 208	\$ 529	\$ 676
Non-cash transactions:			
Unrealized gain / (loss) on marketable securities	(1)	(41)	42
Exchange of equipment loan obligation	—	—	3,968

See notes to consolidated financial statements

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Restatement of Historical Financial Statements

The accompanying Consolidated Balance Sheet as of December 31, 2009 and the Consolidated Statement of Operations, Equity, and Cash Flows for the year ended December 31, 2009, have been restated in this report to reclassify certain warrants based on a reassessment of the applicable accounting guidance, as discussed in Note 2.

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a biotechnology company developing surfactant therapies to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel KL₄ proprietary technology produces a synthetic, peptide-containing surfactant (KL₄ surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol-generating technology (capillary aerosolization technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL₄ surfactant to the lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are developing our lead products, Surfaxin® (lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. In April 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to our New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL₄ surfactant technology. The letter focused primarily on certain aspects of our fetal rabbit biological activity test (BAT, a quality control and stability release test for Surfaxin and our other KL₄ pipeline products), specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time. We met with the FDA at an end-of-review meeting in June 2009 and by teleconference in September 2009 to discuss specific proposals to resolve this sole remaining Chemistry, Manufacturing & Control (CMC) issue, which must be addressed to obtain approval of Surfaxin. Based on these and other interactions with the FDA, we are currently implementing a protocol intended to optimize and revalidate the BAT. This effort is ongoing and, although not necessarily indicative of the final results, the BAT is presently meeting all pre-specified acceptance criteria. Once the BAT is optimized and revalidated, we plan to initiate a comprehensive preclinical program that will consist of a series of side-by-side studies comparing the results of the BAT with those of the well-established preterm lamb model of RDS in order to satisfy the FDA’s requirements with respect to the BAT. If these studies are successful, we believe that we could be in a position to file a Complete Response to the April 2009 Complete Response Letter in the first quarter of 2011, which could lead to approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in 2011. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for use in pediatric medicine.

Surfaxin LS, our lyophilized KL₄ surfactant, is a dry powder formulation that is resuspended as a liquid prior to use and is intended to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. Aerosurf is our proprietary KL₄ surfactant in aerosolized form, which we are developing using our capillary aerosolization technology, initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. If approved, we believe that Aerosurf will make it possible to administer surfactant into the lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of surfactant therapy in pediatric medicine.

In addition to our lead products, we plan over time to develop our KL₄ surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. Our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives

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to fund their further development. We have an ongoing Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF) and our KL₄ surfactant is the subject of an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL₄ surfactant in patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL₄ surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL₄ surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

We are actively assessing various strategic and financial alternatives to secure the necessary capital to advance our KL₄ respiratory pipeline programs to maximize stockholder value, although we prefer to accomplish our objectives through strategic alliances. We are actively engaged in current discussions with potential strategic and/or financial partners, but there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. Until we secure an alliance or other financing alternative, we will continue to focus our financial resources on the potential approval of Surfaxin, while minimizing investments in our other pipeline programs.

Note 2 – Restatement of Financial Statements

We have restated our previously issued consolidated financial statements and related disclosures for the year ended December 31, 2009 to correct errors in the accounting for certain warrants. Specifically, we previously classified as equity instruments warrants that should have been classified as derivative liability instruments based on the terms of the warrants and the applicable accounting guidance.

We have historically accounted for warrants, which prior to May 2009 were issued in private transactions, as equity instruments. Certain warrants issued in registered transactions in May 2009 generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise, generally accepted accounting principles establishes that, in the absence of express agreement of the parties to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the issuer to provide freely-tradable shares in all circumstances. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that an event would trigger cash settlement.

The accompanying 2009 financial statements have been restated to report the warrants issued in May 2009 as derivative liabilities measured at estimated fair value, calculated using the Black-Scholes option pricing model:

Issuance Date	Number of Warrants Issued	Exercise Price	Expiration of Warrants	Fair Value of Warrants at Issuance Date (In thousands)
May 13, 2009	7,000,000	\$1.15	May 13, 2014	\$3,560

The revaluation of the fair value of warrants at each subsequent balance sheet date results in a change in the carrying value of the liability, which is recorded as “Change in fair value of common stock warrant liability” in the consolidated statement of operations. The net effect of these changes for the year ended December 31, 2009, and for each of the quarterly consolidated financial statements for the periods ended June 30, 2009 and September 30, 2009 are as follows:

Reporting Period	Income (Loss) Resulting from Change in Fair Value of Common Stock Warrant Liability (In thousands)	Net Effect on Loss Per Share
Annual		
Year ended December 31, 2009	\$ 369	\$ —
Interim (Unaudited)		
Quarter ended June 30, 2009	(1,323)	(0.01)

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Reporting Period	Income (Loss) Resulting from Change in Fair Value of Common Stock Warrant Liability (In thousands)	Net Effect on Loss Per Share
Quarter ended September 30, 2009	(1,662)	(0.01)
Quarter ended December 31, 2009	3,354	0.03

We have not amended our previously-filed Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009 to correct these misstatements, and thus the financial statements and related financial statement information contained in those reports should no longer be relied upon.

The following tables summarize the effects of the restatement on each affected caption in the accompanying financial statements as of and for the year ended December 31, 2009:

Consolidated Balance Sheet (in thousands)	December 31, 2009 (As previously reported)	December 31, 2009 (As restated)
Current Liabilities:		
Common stock warrant liability	\$ --	\$ 3,191
Total Current Liabilities	15,798	18,989
Total Liabilities	16,916	20,107
Stockholders' Equity:		
Additional paid-in-capital	365,063	361,503
Accumulated deficit	(357,649)	(357,280)
Total stockholders' equity	4,487	1,296

Consolidated Statement of Operations (in thousands)	Year Ended December 31, 2009 (As previously reported)	Year Ended December 31, 2009 (As restated)
Change in fair value of common stock warrant liability	\$ --	\$ 369
Net Loss	(30,240)	(29,871)
Loss Per Share	(0.26)	(0.26)

Consolidated Statement of Cash Flows (in thousands)	Year Ended December 31, 2009 (As previously reported)	Year Ended December 31, 2009 (As restated)
Net Loss	\$ (30,240)	\$ (29,871)
Fair value adjustment of common stock warrants	--	(369)

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Note 3 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our CEFFs, capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through a combination of these sources, as well as sales revenue from our product candidates, beginning with Surfaxin for the prevention of RDS, if approved.

Following receipt of the April 2009 FDA Complete Response Letter for Surfaxin, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL₄ technology through strategic alliances or other collaboration arrangements. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors, which is included in our financial statements in this report, contains a notation related to our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through strategic and collaborative arrangements with potential partners and/or future debt and equity financings, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our December 31, 2009 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

Our future capital requirements will depend upon many factors, including our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL₄ surfactant products to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of December 31, 2009, we had cash and cash equivalents of \$15.7 million. In February 2010, we completed a public offering resulting in gross proceeds of \$16.5 million (\$15.1 million net). Also, as of December 31, 2009, our \$10.5 million loan with Quintiles (formerly PharmaBio Development Inc. and NovaQuest™), a strategic investment group of Quintiles Transnational Corp., is classified as a current liability, payable in April 2010. We are pursuing a potential strategic restructuring of this loan; however, there can be no assurance that any such restructuring will occur. Currently, under our two CEFFs, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. However, as of March 5, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available because the market price of our common stock price was below the minimum price required (\$1.15 and \$0.60, respectively) to utilize the facility. See, Note 10 – Stockholders' Equity, for details about our CEFFs. During 2009, we raised aggregate gross proceeds of \$22.0 million. In May 2009, we completed a public offering of common stock, resulting in gross proceeds of \$11.3 million (\$10.5 million net), and, throughout 2009, we raised an aggregate of \$10.7 million from 10 draw-downs

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under our CEFFs. *See*, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs),” and “– Financings Pursuant to Common Stock Offerings.”

Note 4 – Summary of Significant Accounting Policies and Recent Accounting Pronouncements

The consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States.

Consolidation

The consolidated financial statements include all of the accounts of Discovery Laboratories, Inc. and its inactive subsidiary, Acute Therapeutics, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

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.

Cash, cash equivalents and marketable securities

We consider all highly liquid marketable securities purchased with a maturity of three months or less to be cash equivalents.

Marketable securities are classified as available-for-sale and carried at fair market value, based on quoted market prices for these or similar instruments. Realized gains and losses are computed using the average cost of securities sold. Any appreciation/depreciation on these marketable securities is recorded as other comprehensive income (loss) in the statements of changes in stockholders’ equity until realized. Realized gains (losses) on disposition of marketable securities are recorded in the statement of operations when disposed.

Marketable securities are purchased pursuant to an investment policy approved by our Board of Directors (the Board) that provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs.

Fair Value of Financial Instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities and restricted cash. The fair values of the Company’s cash equivalents and marketable securities are based on quoted market prices. The carrying amount of cash equivalents and marketable securities is equal to their respective fair values at December 31, 2009 and December 31, 2008.

Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which the Company believes approximates fair value.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

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Long-lived assets

Our long-lived assets, primarily consisting of equipment, are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's undiscounted cash flows are less than its carrying value, an impairment is recorded and the asset is written down to its estimated value. No impairment was recorded during the years ended December 31, 2009, 2008 and 2007, as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Revenue recognition under strategic alliances and collaboration agreements

Revenue under strategic alliances and our collaboration agreements is recognized based on the performance requirements of the contract. Upfront, non-refundable license fees received in connection with collaboration agreements are deferred and recognized as revenue over the life of the agreement or period of performance obligations. Revenues derived from the achievement of milestones are recognized when the milestone is achieved, as long as there are no further performance obligations. Deferred revenue results from cash received or amounts receivable in advance of revenue recognition based upon the performance requirements of the contract. Grant revenue is recorded upon receipt of funds.

Research and development

Research and development costs consist primarily of expenses associated with our personnel, facilities, manufacturing operations, formulation development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

Stock-based compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of Accounting Standards Codification (ASC) Topic 718 "*Stock Compensation*," using the modified-prospective-transition method. See, Note 11 – Stock Options and Stock-based Employee Compensation, for a detailed description of our recognition of stock-based compensation expense.

Warrant accounting

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. In compliance with applicable securities law, registered common stock warrants that require the issuance of registered shares upon exercise and do not sufficiently preclude an implied right to cash settlement are accounted for as derivative liabilities. We classify these derivative warrant liabilities on the consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes pricing model to value the derivative warrant liability. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

Income taxes

We provide for income taxes in accordance with Accounting Standards Codification (ASC) Topic 740, "*Accounting for Income Taxes*". ASC Topic 740 requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities.

We use 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. The adoption of ASC 740 on January 1, 2007 did not have a material impact on the consolidated financial statements. Due to the fact

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that we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

Comprehensive Loss

Comprehensive loss consists of net loss plus the changes in unrealized gains and losses on available-for-sale securities. Comprehensive loss for the years ended December 31, 2009, 2008 and 2007 are as follows:

(in thousands)

	2009	December 31, 2008	2007
	(As Restated)		
Net loss	\$ (29,871)	\$ (39,106)	\$ (40,005)
Change in unrealized (losses)/gains on marketable securities	(1)	(41)	42
Comprehensive loss	<u>\$ (29,872)</u>	<u>\$ (39,147)</u>	<u>\$ (39,963)</u>

Net loss per common share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding for the periods. For the years ended December 31, 2009, 2008 and 2007, 30.9 million, 25.1 million and 20.3 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants and vesting of restricted stock awards. Due to our net loss, these potentially issuable shares were not included in the calculation of diluted net loss per share as the effect would be anti-dilutive, therefore basic and dilutive net loss per share are the same.

Business segments

We currently operate in one business segment, which is the research and development of products focused on surfactant replacement therapies for respiratory disorders and diseases. We are managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. We do not operate separate lines of business with respect to our product candidates.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued *the Accounting Standards Codification*TM (the Codification). The Codification now is the single source of authoritative accounting principles recognized by FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with Generally Accepted Accounting Principles (GAAP), in the United States. The Codification became effective for interim and annual periods ending after September 15, 2009. All other accounting literature not included in the Codification will be nonauthoritative, except for additional authoritative rules and interpretive releases issued by the United States Securities Exchange Commission (SEC). The Codification is not intended to change GAAP; instead, it reorganizes the thousands of US GAAP pronouncements into approximately 90 Accounting Topics. Adoption of the Codification did not have an impact on our consolidated financial statements.

In May 2009, FASB issued new guidance for accounting for subsequent events. The new guidance, which is now part of Accounting Standards Codification (ASC) Topic 855, *Subsequent Events*, is consistent with existing auditing standards in its definition of subsequent events, but requires disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. There are two types of subsequent events: (1) events that provide additional evidence about conditions that existed at the balance sheet date, and are recognized in the financial statements, and (2) events that provide evidence about conditions that did not exist at the balance sheet date, but arose before the financial statements are issued or are available to be issued, and are not recognized at the balance sheet date. The adoption of the new guidance had no impact on our consolidated financial statements. We evaluated all events or transactions that occurred after December 31, 2009 up through March 10, 2010, the date

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these financial statements were issued and filed with the SEC. During this period we had three material nonrecognized subsequent events, which are described in Note 18.

In December 2007, FASB issued new guidance for accounting for collaborative arrangements. The new guidance, which is now part of ASC Topic 808, *Collaborative Arrangements*, is effective for fiscal years beginning after December 15, 2008. The scope of the new guidance is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The new guidance requires certain income statement presentation of transactions with third parties and of payments between parties to the arrangement, along with disclosure about the nature and purpose of the arrangement. The adoption of the new guidance on January 1, 2009 did not have a material impact on our consolidated financial statements.

In December 2007, FASB issued new guidance for accounting for business combinations. The new guidance, which is now part of ASC topic 805, *Business Combinations*, is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. The new guidance establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree, and the goodwill acquired in the business combination. ASC Topic 805 also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. We adopted the new guidance on January 1, 2009, which had no immediate impact on our financial statements; however, it may have an impact on the accounting for any potential future business combinations.

Note 5 – Fair Value Measurements

ASC Topic 820, Fair Value Measurements and Disclosures establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets and liabilities. Level 1 is generally considered the most reliable measurement of fair value under ASC 820.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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Fair Value on a Recurring Basis

Assets and liabilities measured at fair value on a recurring basis are categorized in the table below as of December 31, 2009:

<i>(in thousands)</i>	Fair Value	Fair value measurement using		
	December 31, 2009	Level 1	Level 2	Level 3
Assets:				
Money markets (1)	\$ 14,690	\$ 14,690	\$ —	\$ —
Certificate of deposit	600	600	—	—
Total Assets	<u>\$ 15,290</u>	<u>\$ 15,290</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities				
Common stock warrant liability	<u>\$ 3,191</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,191</u>

(1) Dreyfus Treasury & Agency Cash Management Fund.

The following table summarizes the activity of Level 3 inputs measured on a recurring basis for the year ended December 31, 2009:

<i>(in thousands)</i>	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2008	\$ -
Issuance of common stock warrants	3,560
Change in fair value of common stock warrant	(369)
Balance at December 31, 2009	<u>\$ 3,191</u>

Note 6 – Marketable Securities

We did not hold any available-for-sale marketable securities as of December 31, 2009. The following is a summary of available-for-sale marketable securities as of December 31, 2008 and 2007:

<i>(in thousands)</i>	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
<u>December 31, 2008</u>				
U.S. treasury notes	\$ 2,047	\$ 1	\$ —	\$ 2,048
Total	<u>\$ 2,047</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ 2,048</u>
<u>December 31, 2007</u>				
Commercial paper	\$ 16,010	\$ 42	\$ —	\$ 16,052
Certificates of deposit	26	—	—	26
Total	<u>\$ 16,036</u>	<u>\$ 42</u>	<u>\$ —</u>	<u>\$ 16,078</u>

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Available-for-sale marketable securities consist of United States treasury notes, certificates of deposits, and high-quality commercial paper with a maturity of greater than three months. All available-for-sale marketable securities have a maturity period of less than one year. These assets are measured at fair market value at each reporting period. The fair market value is recorded using quoted prices from active markets.

Marketable securities are purchased pursuant to an investment policy approved by our Board that provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs.

Note 7 – Restricted Cash

Restricted cash consists of a security deposit held by our bank in the amount of \$600,000 to secure a letter of credit in the same notional amount held by our landlord to secure our obligations under our Lease Agreement dated May 26, 2004 for our headquarters location in Warrington, Pennsylvania (*See*, Note 14 – Commitments, for further discussion on our leases). Under the terms of our Lease, beginning in March 2010, the letter of credit (and the related security deposit) will be reduced to \$400,000 and will remain in effect at that level 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 and the security deposit will be released.

Note 8 – Property and Equipment

Property and equipment as of December 31, 2009 and 2008 was comprised of the following:

<i>(in thousands)</i>	December 31,	
	2009	2008
Equipment	\$ 7,265	\$ 7,143
Furniture	791	791
Leasehold improvements	2,838	2,813
Subtotal	10,894	10,747
Accumulated depreciation and amortization	(6,226)	(4,782)
Property and equipment, net	<u>\$ 4,668</u>	<u>\$ 5,965</u>

Equipment primarily consists of: (i) manufacturing equipment to produce our KL₄ surfactant products, including Surfaxin and Aerosurf, for use in our preclinical studies, clinical trials and potential commercial needs; (ii) laboratory equipment for manufacturing, analytical, research and development activities; and (iii) computers and office equipment to support our overall business activities.

Leasehold improvements primarily consists of construction of a new analytical and development laboratory in our Warrington, Pennsylvania headquarters, which was completed in 2007 and where we consolidated the analytical, quality and development activities previously located in Doylestown, Pennsylvania, and Mountain View, California. The activities conducted in our laboratory include release and stability testing of raw materials as well as preclinical, clinical and, if approved, commercial drug product supply. We also perform development work with respect to our aerosolized KL₄ surfactant and novel formulations of our KL₄ surfactant technology. The laboratory will be amortized through the end of the lease term for our Warrington, Pennsylvania headquarters in 2013. In addition, in 2007, we built a microbiology laboratory at our manufacturing facility in Totowa, New Jersey, to support production of our drug product candidates. The microbiology laboratory will be amortized through the end of the lease term for our Totowa, New Jersey facility in 2014.

Depreciation and amortization expense on property and equipment for the years ended December 31, 2009, 2008, and 2007 was \$1.4 million, \$1.6 million, and \$1.5 million, respectively.

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Note 9 – Accrued Expenses

Accrued expenses as of December 31, 2009 and 2008 were comprised of the following:

<i>(in thousands)</i>	December 31,	
	2009	2008
Accrued compensation ⁽¹⁾	\$ 1,763	\$ 2,390
Accrued manufacturing	568	1,174
Accrued research and development	332	374
All other accrued expenses	783	1,375
Total accounts payable and accrued expenses	<u>\$ 3,446</u>	<u>\$ 5,313</u>

Accrued compensation consists of potential employee incentive arrangements (pursuant to plans approved by our Board), contractual future severance arrangements for our former President and Chief Executive Officer (*see*, Note 14 – Commitments, for further discussion of this arrangement) and existing union employees at our manufacturing operations, and employees' unused earned vacation.

Note 10 Debt

Loan Payable – Quintiles

Quintiles (formerly PharmaBio Development, Inc. and NovaQuest™) in 2001 extended to us a secured, revolving credit facility, which we restructured in October 2006. The outstanding principal balance of the loan, \$8.5 million, is due and payable on April 30, 2010, together with all unpaid interest accrued since July 1, 2006. Since October 2006, interest is calculated at the prime rate, compounded annually. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. In addition, our obligations to Quintiles under the loan agreement are secured by a security interest in substantially all of our assets, subject to limited exceptions set forth in the related security agreement.

Also in October 2006, in consideration of Quintiles's agreement to restructure the loan, we entered into a Warrant Agreement with Quintiles, pursuant to which Quintiles has the right to purchase 1.5 million shares of our common stock at an exercise price of \$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 Quintiles 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.

As of December 31, 2009, the outstanding balance under the loan was \$10.5 million (\$8.5 million principal and \$2.0 million accrued interest) and was classified as a current liability on the Consolidated Balance Sheet as of such date.

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the Quintiles loan of \$0.3 million, \$0.5 million and \$0.7 million, respectively. The decrease in interest expense in 2009 and 2008 is due to declines in the prime rate during 2008 ranging from 7.25% to 3.25%. During 2009, the prime rate remained at 3.25%. In addition, for the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with the amortization of deferred financing costs in connection with warrants issued to Quintiles in October 2006 of \$0.5 million, \$0.5 million and \$0.5 million, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Equipment Loans

Our equipment loan liabilities as of December 31, 2009 and 2008 are as follows:

<i>(in thousands)</i>	<u>2009</u>	<u>2008</u>
GE Business Financial Services, Inc.		
Short-term	\$ 538	\$ 2,385
Long-term	<u>65</u>	<u>664</u>
Total	603	3,049
 Pennsylvania Machinery and Equipment Loan		
Short-term	59	57
Long-term	<u>363</u>	<u>428</u>
Total	422	485
 Total Short-term	597	2,442
Total Long-term	<u>428</u>	<u>1,092</u>
Total	<u>\$ 1,025</u>	<u>\$ 3,534</u>

For the years ended December 31, 2009, 2008 and 2007, we incurred interest expense associated with our equipment loans of \$0.2 million, \$0.6 million and \$0.6 million, respectively.

Equipment Financing Facility with GE Business Financial Services Inc.

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide a \$12.5 million facility (Facility) to fund our capital programs. The right to draw under this Facility expired on November 30, 2008. Over the term of the Facility, we received \$7.2 million, \$4.0 million of which was applied to prepayment of a prior facility and \$2.3 million of which was associated with construction and equipment for the analytical and development laboratory that we built in our Warrington, Pennsylvania headquarters in 2007.

Advances under the Facility to finance the acquisition of property and equipment are amortized over a period of 36 months and all other equipment and related costs are amortized over a period of 24 months. The advance to prepay our prior facility is amortized over a period of 27 months. Interest on each advance accrues at a fixed rate per annum equal to one-month LIBOR plus 6.25%, determined on the funding date of such advance. Principal and interest on all advances are 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%.

Our obligations under the Facility are secured by a security interest in (i) the financed property and equipment, and (ii) all of our intellectual property (Supplemental Collateral), subject to limited exceptions set forth in the Loan Agreement. The Supplemental Collateral will be released on the earlier to occur of (a) receipt by us of FDA approval of our NDA for Surfaxin for the prevention of RDS in premature infants, or (b) 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, GE and Quintiles entered into an Intercreditor Agreement under which GE 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 Quintiles as discussed above.

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Pennsylvania Machinery and Equipment Loan Fund (MELF)

We entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), effective September 8, 2008, pursuant to which the Department made a loan to us from the Machinery and Equipment Loan Fund in the amount of \$500,000 (MELF Loan) to fund the purchase and installation of new machinery and equipment and the upgrade of existing machinery and equipment at our analytical and development laboratory in Warrington, Pennsylvania. Principal and interest on the MELF Loan is payable in equal monthly installments over a period of seven years. Interest on the principal amount accrues at a fixed rate of five percent (5.0%) per annum. We may prepay the MELF Loan at any time without penalty.

In addition to customary terms and conditions, the MELF Agreement provides that we must meet certain criteria regarding retention and creation of new jobs within a three-year period. In the event that we fail to comply with this requirement, the interest rate on the Promissory Note, except in limited circumstances, will be adjusted to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Note 11 – Stockholders' Equity

Registered Public Offerings and Private Placements

In February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of \$0.60 per unit, resulting in gross and net proceeds to us of \$16.5 million and \$15.1 million, respectively. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of \$0.85, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis. This offering was made pursuant to the 2008 Universal Shelf (*see*, Universal Shelf Registration Statements of this Note).

In May 2009, we completed a registered direct offering of 14,000,000 shares of our common stock and warrants to purchase 7,000,000 shares of our common stock, sold as units to select institutional investors, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at an offering price of \$0.81 per unit, resulting in gross and net proceeds to us of \$11.3 million and \$10.5 million, respectively. The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of \$1.15, for cash or, in the event that the related registration statement or an exemption from registration is not available for the resale of the warrant shares, on a cashless basis. This offering was made pursuant to our 2008 Universal Shelf.

In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors. The shares were priced at \$2.50 per share resulting in gross and net proceeds to us of \$25.0 million and \$23.6 million, respectively. This offering was made pursuant to the 2005 Universal Shelf (*see*, Universal Shelf Registration Statements of this Note).

In April 2007, we completed 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 and net proceeds to us of \$30.2 million and \$28.1 million, respectively. This offering was made pursuant to our 2005 Universal Shelf.

Committed Equity Financing Facilities (CEFFs)

We have entered into four Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under which Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allow us, at our discretion, to raise capital at the time and in amounts deemed suitable to us, to support our business plans. We are not obligated to utilize any of the funds available under the CEFFs. Each CEFF is available for a period of 2 to 3 years from inception. Should we choose to utilize any of the CEFFs, our ability to access the funds available under the CEFFs is subject to certain conditions, including stock price and volume limitations.

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As of December 31, 2009, we had two CEFFs available for future financings as follows: the CEFF dated December 12, 2008 (December 2008 CEFF) and the CEFF dated May 22, 2008 (May 2008 CEFF). A third CEFF entered in April 2006 expired on May 12, 2009 and is no longer available. The following table sets forth an overview of the “draw down” requirements and availability under each CEFF:

<i>(in millions, except per share data and trading days)</i>		Minimum Price to Initiate Draw Down ⁽¹⁾	Minimum VWAP for Daily Pricing ⁽²⁾	# of Trading Days In Each Draw Down ⁽²⁾	Amount per Contract		Potential Availability at December 31, 2009	
Expiration					Shares	Maximum Proceeds	Shares	Maximum Proceeds
May 2008 CEFF	June 18, 2011	\$1.15	90% of the closing market price on the day preceding the first day of draw down	8	19.3	\$60.0	12.8	\$51.8
Dec. 2008 CEFF	Feb. 6, 2011	\$0.60		6	15.0	\$25.0	7.1	\$17.7

- (1) To initiate a draw down, the closing price of our common stock on the trading day immediately preceding the first trading day of the draw down period must be at least equal to the minimum price set forth above.
- (2) If on any trading day, the daily volume-weighted average of our common stock (VWAP) is less than the minimum VWAP set forth above, no shares are purchased on that trading day and the aggregate amount that we originally designated for the overall draw down is reduced for each such day by 1/8th in the case of the December 2008 CEFF, and 1/6th in the case of the May 2008 CEFF, respectively. Unless we and Kingsbridge agree 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.

Each draw down is limited in amount as follows:

- May 2008 CEFF – the lesser of 3.0 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or \$10 million; and
- December 2008 CEFF – the lesser of 1.5 percent of the closing price market value of the outstanding shares of our common stock at the time of the draw down or \$3 million.

The purchase price of shares sold to Kingsbridge under the CEFFs is at a discount to the VWAP (as defined in the applicable agreement) for each of the trading days following our initiation of a “draw down” under the CEFF, as follows:

<u>Daily VWAP</u>	<u>% of VWAP</u>	<u>Applicable Discount</u>
May 2008 CEFF		
Greater than \$7.25 per share	94%	6%
Less than or equal to \$7.25 but greater than \$3.85 per share	92%	8%
Less than or equal to \$3.85 but greater than \$1.75 per share	90%	10%
Less than or equal to \$1.75 but greater than or equal to \$1.15 per share	88%	12%
December 2008 CEFF		
Greater than \$7.25 per share	94%	6%
Less than or equal to \$7.25 but greater than \$3.85 per share	92%	8%
Less than or equal to \$3.85 but greater than \$1.75 per share	90%	10%
Less than or equal to \$1.75 but greater than or equal to \$1.10 per share	88%	12%
Less than or equal to \$1.10 but greater than or equal to \$.60	85%	15%

In addition, Kingsbridge may terminate the CEFFs under certain circumstances, including if a material adverse event relating to our business continues for 10 trading days after notice of the material adverse event.

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In connection with the December 2008 CEFF, we issued a warrant to Kingsbridge on December 22, 2008 to purchase up to 675,000 shares of our common stock at an exercise price of \$1.5132 per share. The warrant expires in May 2014 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$1.0 million. As of December 31, 2009, this warrant had not been exercised.

In connection with the May 2008 CEFF, we issued a warrant to Kingsbridge on May 22, 2008 to purchase up to 825,000 shares of our common stock at an exercise price of \$2.506 per share. The warrant expires in November 2013 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.1 million. As of December 31, 2009, this warrant had not been exercised.

In connection with the 2006 CEFF, we issued a Class C Investor Warrant to Kingsbridge on April 17, 2006 to purchase up to 490,000 shares of our common stock at an exercise price equal to \$5.6186 per share. The warrant expires in October 2011 and is exercisable, in whole or in part, for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.8 million. As of December 31, 2009, this Class C Investor Warrant had not been exercised.

In connection with a CEFF that we entered in 2004, 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 expired unexercised in January 2010.

CEFF Financings

The financings that we completed under the December 2008 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
April 8, 2009	806	\$ 1,000	\$ 1.24
May 7, 2009	1,273	1,000	0.79
September 23, 2009	1,793	1,583	0.88
October 13, 2009	1,909	1,800	0.94
October 21, 2009	2,101	1,900	0.90

The financings that we completed under the May 2008 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
July 11, 2008	1,105	\$ 1,563	\$ 1.41
July 31, 2008	992	1,500	1.51
October 17, 2008	914	1,313	1.44
November 20, 2008	221	250	1.13
January 2, 2009	479	500	1.04
January 16, 2009	419	438	1.04
February 18, 2009	857	1,000	1.17
March 31, 2009	1,015	1,094	1.08
October 13, 2009	559	606	1.09

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The financings that we completed under the now expired 2006 CEFF are:

(in thousands, except per share data)

<u>Completion Date</u>	<u>Shares Issued</u>	<u>Gross Proceeds</u>	<u>Discounted Average Price Per Share</u>
May 29, 2006	1,079	\$ 2,188	\$ 2.03
October 11, 2006	1,205	2,300	1.91
November 10, 2006	1,372	3,000	2.19
February 22, 2007	943	2,000	2.12
October 12, 2007	1,909	5,000	2.62
September 9, 2008	676	1,250	1.85

401(k) Employer Match

We have a voluntary 401(k) savings plan covering eligible employees that allows for periodic discretionary matches as a percentage of each participant's contributions (up to the maximum deduction allowed, excluding "catch up" amounts) in newly issued shares of common stock. For the years ended December 31, 2009, 2008 and 2007, the match resulted in the issuance of 346,904, 231,287, and 118,330 shares of common stock, respectively.

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Common Shares Reserved for Future Issuance

Common shares reserved for potential future issuance upon exercise of warrants

The chart below summarizes shares of our common stock reserved for future issuance upon the exercise of warrants.

(in thousands, except price per share data)

	December 31,		Exercise	Expiration
	2009	2008	Price	Date
Investor Warrants – May 2009 Financing ⁽¹⁾	7,000	-	\$ 1.15	5/13/2014
Kingsbridge – December 2008 CEFF ⁽²⁾	675	675	\$ 1.51	6/12/2014
Kingsbridge – May 2008 CEFF ⁽²⁾	825	825	\$ 2.51	11/22/2013
Private Placement – 2006 ⁽³⁾	2,315	2,315	\$ 3.18	11/22/2011
Quintiles - 2006 Loan Restructuring ⁽⁴⁾	1,500	1,500	\$ 3.58	10/26/2013
Class C Investor Warrants - 2006 CEFF ⁽²⁾	490	490	\$ 5.62	10/17/2011
Quintiles - 2004 Partnership Restructuring ⁽⁵⁾	850	850	\$ 7.19	11/3/2014
Class B Investor Warrants - 2004 CEFF ⁽²⁾	375	375	\$ 12.07	1/6/2010
Class A Investor Warrants – 2003	809	809	\$ 6.88	9/19/2010
Total	14,839	7,839		

⁽¹⁾ Refer to the Registered Public Offerings and Private Placements section of this Note.

⁽²⁾ Refer to the Registered Public Offerings and Private Placements section of this Note.

⁽³⁾ In Nov. 2006, in connection with a sale of 4.6 million shares of our common stock, we issued warrants to purchase common stock at an exercise price equal to \$3.18 per share. The warrants expire in Nov. 2011 and, subject to an aggregate share ownership limitation, are exercisable, in whole or in part, for cash, except in limited circumstances, with expected proceeds to us of \$7.4 million. As of December 31, 2009, the warrants had not been exercised

⁽⁴⁾ Refer to Note 9 – Debt

⁽⁵⁾ Issued in connection with a restructuring of a 2003 arrangement with Quintiles Transnational Corp that resulted in cancellation of a 2001 commercialization agreement and extension of the Quintiles Loan. Refer to Note 9 – Debt.

Common shares reserved for potential future issuance upon exercise of stock options

In June 2007, our stockholders approved the adoption of the 2007 Long-Term Incentive Plan (the “2007 Plan”). The 2007 Plan provides for the grant of long-term equity and cash incentive compensation awards and replaced the Amended and Restated 1998 Stock Incentive Plan (the “1998 Plan”) whose ten-year term was to expire in March 2008. The 2007 Plan continues many of the features of the 1998 Plan, but is updated to reflect changes to Nasdaq rules regarding equity compensation, other regulatory changes and market and corporate governance developments. Awards outstanding under the 1998 Plan will continue to be governed by the terms of the 1998 Plan and the agreements under which they were granted.

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Stock options outstanding and available for future issuance as of December 31, 2009 and 2008 are as follows:

<i>(in thousands)</i>		As of December 31,	
		2009	2008
2007 Plan			
Outstanding		6,688	7,296
Available for Future Grants		1,812	1,204
Total		8,500	8,500
1998 Plan			
Outstanding		9,298	9,916
Available for Future Grants		—	—
Total		9,298	9,916
Total Outstanding		15,986	17,212
Total Available for Future Grants		1,812	1,204
Total		17,798	18,416

The 1998 Plan was suspended upon approval of the 2007 Plan in June 2007; therefore, no shares were available for future grants under the 1998 Plan. *See*, Note 11 – Stock Options and Stock-based Employee Compensation.

Universal Shelf Registration Statements

2008 Universal Shelf

In June 2008, we filed a universal shelf registration statement on Form S-3 (No. 333-151654) (“2008 Universal Shelf”) with the SEC for the proposed offering from time to time of up to \$150 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at that time. As of December 31, 2009 and March 1, 2010, respectively, up to \$138.7 million and \$122.2 million of our securities are potentially available for issuance pursuant to the 2009 Universal Shelf. *See*, Registered Public Offering and Private Placements in this Note for offerings made pursuant to the 2008 Universal Shelf.

2005 Universal Shelf

In October 2005, we filed a universal shelf registration statement on Form S-3 (File No. 333-128929) (2005 Universal Shelf) with the SEC for the proposed offering, from time to time, of up to \$100 million of our debt or equity securities. *See*, Registered Public Offering and Private Placements in this Note for a discussion of offerings pursuant to the 2008 Universal Shelf. The October 2005 Universal Shelf expired in December 2008.

Common shares reserved for potential future issuance under CEFF arrangements

As of December 31, 2009, the Company had two CEFFs available for future financings, as follows:

<i>(in thousands)</i>		Potential future issuance as of December 31,	
		2009	2008
	Expiration		
May 2008 CEFF	June 18, 2011	12,768	15,618
December 2008 CEFF	February 6, 2011	7,118	15,000

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Common shares reserved for potential future issuance under our 401(k) Plan

In September 2009 and December 2008, our Board approved an increase of 160,000 and 350,000 shares, respectively, to the reserve for issuance under the 401(k) Plan. As of December 31, 2009 and 2008, we had 137,435 and 324,339 shares, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 12 – Stock Options and Stock-based Employee Compensation

Long-Term Incentive Plans

In June 2007, our stockholders approved the 2007 Plan, which replaced the 1998 Plan, which by its terms would have expired in March 2008. *See*, Note 10 – Common shares reserved for potential future issuance upon exercise of stock options. The purposes of the 2007 Plan are to (i) encourage eligible participants to acquire a proprietary interest in our company, (ii) provide employees incentives to contribute to our future success, thereby enhancing stockholder value, and (iii) attract and retain exceptionally qualified individuals upon whom, in large measure, our sustained progress, growth and profitability depend.

Under the 2007 Plan, we may grant awards for up to 8,500,000 shares of our common stock. An administrative committee (the Committee – currently the Compensation Committee of the Board) or Committee delegates may determine the types, the number of shares covered by, and the terms and conditions of, such awards. Eligible participants may include any of our employees, directors, advisors or consultants.

The 2007 Plan continues many of the features of the 1998 Plan, but is updated to reflect changes to Nasdaq rules regarding equity compensation, other regulatory changes and market and corporate governance developments. Awards outstanding under the 1998 Plan continue to be governed by the terms of that plan and the applicable award agreements.

Award under the two plans may include:

Stock Options and Stock Appreciation Rights (SARs)

The Committee may award nonqualified stock options, incentive stock options, or SARs with a term of not more than ten years and a purchase price not be less than 100% of the fair market value on the date of grant. The Committee will establish the vesting schedule for stock options and the method of payment for the exercise price, which may include cash, shares, or other awards. Although individual grants may vary, option awards generally are exercisable upon vesting, vest based upon three years of continuous service and have a 10-year term. In addition, the 2007 Plan provides for limits on the number of options and SARs granted to any one participant and the terms of any incentive stock option must comply with the provisions of Section 162(m) of the Internal Revenue Code.

Restricted Stock and Restricted Stock Units

The Committee may grant restricted stock awards (RSAs) and restricted stock units and, among other things, establish the applicable restrictions, including any limitation on voting rights or the receipt of dividends, and will establish the manner and timing under which restrictions may lapse. If employment is terminated during the applicable restriction period (other than as a result of death or disability), shares of restricted stock and restricted stock units still subject to restriction will be forfeited, except as determined otherwise by the Committee.

Performance Awards and Other Stock-Based Awards

The Committee may grant performance awards, which may be denominated in cash, shares, other securities or other awards and payable to, or exercisable by, the participant upon the achievement of performance goals during performance periods, as established by the Committee. The Committee may grant other stock-based

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awards that are denominated or payable in shares, under the terms and conditions as the Committee will determine. The Committee may decide to include dividends or dividend equivalents as part of a performance or other stock-based award, and may accrue dividends, with or without interest, until the award is paid.

Automatic Grant of Non-Employee Director Options

Each non-employee directors is entitled to automatic option grants on specified dates as follows: (i) options to purchase 40,000 shares on the date of first election or appointment to the board and (ii) options to purchase 30,000 shares on the date of each subsequent annual stockholders meeting if such director continues to, and has served as a director for at least six months. Non-employee director options vest on the first anniversary of the date of grant (subject to continued service through such date) and will otherwise vest in full upon the termination of service as a result of death or disability. Non-employee director options have a term of ten years (subject to earlier termination twelve months after any termination of service).

No SARs or Performance Awards have been granted under either plan. No RSAs have been granted under the 2007 Plan. Under the 1998 Plan, in 2007, 56,660 RSAs were granted to certain employees for no cash consideration. These RSAs initially were to vest on the date that Surfaxin for RDS first becomes widely commercially available; however, the Committee amended the vesting provisions in 2009 to provide for vesting on the third anniversary of the grant date. As of December 31, 2009, there were 27,500 unvested restricted stock awards outstanding, which vested on January 3, 2010.

Under the 2007 Plan, as of December 31, 2009, options to purchase 6,687,719 shares of common stock were outstanding and 1,812,281 shares were available for potential future grants. As of December 31, 2008, options to purchase 7,295,667 shares of common stock were outstanding and 1,204,333 shares were available for potential future grants. Under the 1998 Plan, options to purchase 9,297,792 and 9,916,644 shares of common stock were outstanding as of December 31, 2009 and December 31, 2008, respectively. No shares are available for future grants under the 1998 Plan.

A summary of option activity under the 2007 Plan and 1998 Plan as of December 31, 2009 and changes during the periods ended December 31, 2007, 2008 and 2009, respectively, is presented below:

			Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
<i>(in thousands, except for weighted-average data)</i>				
Stock Options	Price Per Share	Shares		
Outstanding at December 31, 2006	\$0.19 – \$10.60	10,690	\$ 4.89	
Granted	2.08 – 3.58	3,907	2.94	
Exercised	0.19 – 2.46	(61)	1.72	
Forfeited or expired	0.19 – 9.80	(606)	5.07	
Outstanding at December 31, 2007	\$0.19 – \$10.60	13,930	\$ 4.35	
Granted	1.21 – 2.90	3,950	1.78	
Exercised	0.32 – 1.62	(18)	1.21	
Forfeited or expired	0.19 – 10.60	(650)	5.17	
Outstanding at December 31, 2008	\$0.81 – \$10.43	17,212	\$ 3.72	
Granted	0.49 – 1.18	297	0.78	
Exercised	--	--	--	
Forfeited or expired	0.81 – 9.17	(1,523)	2.63	
Outstanding at December 31, 2009	\$0.49 – \$10.43	15,986	\$ 3.76	6.1
Exercisable at December 31, 2009	\$1.15 – \$10.43	13,608	\$ 4.09	5.7

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Based upon application of the Black-Scholes option-pricing formula described below, the weighted-average grant-date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was \$0.56, \$0.88 and \$2.05, respectively. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was \$0, \$13,000 and \$57,000, respectively. The total intrinsic value of options outstanding, vested and exercisable as of December 31, 2009 is \$13,000, \$0 and \$0, respectively.

A summary of the status of our nonvested shares issuable upon exercise of outstanding options and changes during 2009 is presented below:

<i>(shares in thousands)</i>	Option Shares	Weighted- Average Grant- Date Fair Value
Non-vested at December 31, 2008	6,607	\$ 1.40
Granted	297	.56
Vested	(3,636)	1.55
Forfeited	(891)	1.33
Non-vested at December 31, 2009	<u>2,377</u>	<u>\$ 1.11</u>

The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2009:

<i>(shares in thousands)</i>		Outstanding		Vested and Exercisable		
Price per share	Shares	Weighted- Average Price per Share	Weighted- Average Remaining Contractual Life	Shares	Weighted- Average Price per Share	Weighted- Average Remaining Contractual Life
\$0.49 – \$2.00	4,148	\$1.63	7.86 Years	2,404	\$1.69	7.23 years
\$2.01 – \$4.00	7,463	\$2.66	6.41 Years	6,829	\$2.65	6.44 years
\$4.01 – \$6.00	657	\$4.75	0.88 Years	657	\$4.75	0.88 years
\$6.01 – \$8.00	1,350	\$6.87	5.26 Years	1,350	\$6.87	5.26 years
\$8.01 – \$10.00	2,343	\$8.93	4.24 Years	2,343	\$8.93	4.24 years
\$10.01 – \$10.43	<u>25</u>	\$10.43	4.22 Years	<u>25</u>	\$10.43	4.22 years
	<u>15,986</u>			<u>13,608</u>		

Stock-Based Compensation

As a result of adopting Accounting Standards Codification (ASC) Topic 718 “*Stock Compensation*,” on January 1, 2006, we recognized compensation expense for the years ended December 31, 2009, 2008 and 2007 of \$2.7 million, \$4.6 million and \$5.3 million, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Stock-based compensation expenses was classified as follows:

<i>(in thousands)</i>	Years Ended December 31,		
	2009	2008	2007
Research and development	\$ 649	\$ 1,501	\$ 1,706
General and administrative	2,035	3,127	3,613
Total	<u>\$ 2,684</u>	<u>\$ 4,628</u>	<u>\$ 5,319</u>

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

	Years Ended December 31,		
	2009	2008	2007
Weighted average expected volatility	99%	81%	88%
Weighted average expected term	4.7 years	4.6 years	4.8 years
Weighted average risk-free interest rate	1.7%	2.1%	4.8%
Expected dividends	—	—	—

The total fair value of the underlying shares of the options vested during 2009, 2008, and 2007 equals \$5.6 million, \$4.7 million and \$4.9 million, respectively. As of December 31, 2009, there was \$2.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.37 years.

On August 13, 2009, Dr. Robert J. Capetola, our former President and Chief Executive Officer, resigned his position and with us and as a member of our Board. Under the terms of a Separation of Employment Agreement and General Release dated August 13, 2009 between Dr. Capetola and ourselves, all of Dr. Capetola's outstanding RSAs and options immediately vested and all such RSAs and options shall remain exercisable to the end of their stated terms. During 2009, the company recognized \$0.3 million in stock option modification costs related to these items.

Note 13 – Corporate Partnership, Licensing and Research Funding Agreements

Laboratorios del Dr. Esteve, S.A.

We have a strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of a broad portfolio of potential surfactant products in Andorra, Greece, Italy, Portugal, and Spain. Esteve will pay us a transfer price on sales of Surfaxin and other KL₄ surfactant products. 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 territory. Esteve is obligated 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 territory. As part of a restructuring of this alliance in December 2004, we regained full commercialization rights to our KL₄ surfactant technology in portions of the original territory licensed to Esteve, including key European markets, Central America, and South America (Former Esteve Territories) and 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 strategic collaborations for the development and commercialization of certain of our KL₄ surfactant products, including Surfaxin and Aerosurf in the Former Esteve Territories.

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Licensing and Research Funding Agreements

Philip Morris USA Inc. and Philip Morris Products S.A.

In March 2008, we restructured our December 2005 strategic alliance with Philip Morris USA Inc. (PMUSA), d/b/a Chrysalis Technologies (Chrysalis), and assumed full responsibility from Chrysalis for the further development of the capillary aerosolization technology, including finalizing design development for the initial prototype aerosolization device platform and disposable dose packets. In connection with the restructuring, we restated our prior agreement as of March 28, 2008 and entered into an Amended and Restated License Agreement with PMUSA with respect to the United States (U.S. License Agreement), and, as PMUSA had assigned to Philip Morris Products S.A. (PMPSA) all rights in and to the capillary aerosolization technology outside of the United States (International Rights), effective on the same date, we entered into a License Agreement with PMPSA with respect to the International Rights (International License Agreement) on substantially the same terms and conditions as the U.S. License Agreement. We currently hold exclusive licenses to the capillary aerosolization technology both in and outside of the United States for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, the Exclusive Field). In addition, under the U.S. License Agreement, our license to use the capillary aerosolization technology includes other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions.

As part of the restructuring, Chrysalis completed a technology transfer, provided development support to us through June 30, 2008, and also paid us \$4.5 million to support our future development activities. We are obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field in the territories. In connection with exclusive undertakings of PMUSA and PMPSA not to exploit the capillary aerosolization technology for all licensed uses, we are obligated to pay royalties on all product sales, including sales of aerosol devices and related components that are not based on the capillary aerosolization technology; provided, however, that no royalties are payable to the extent that we exercise our right to terminate the license with respect to a specific indication. We also agreed in the future to pay minimum royalties, but are entitled to a reduction of future royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned in prior periods.

Johnson & Johnson and Ortho Pharmaceutical Corporation

We, Johnson & Johnson and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, are parties to an agreement granting to us an exclusive worldwide license to the proprietary KL₄ surfactant technology, including Surfaxin, in exchange for certain license fees, milestone payments aggregating up to \$2,500,000 and royalties. To date, we have paid \$450,000 of such amount for milestones that have been achieved.

Note 14 – Commercial Strategy and Cost Containment Measures

Following receipt of the April 2009 Complete Response Letter for Surfaxin for the prevention of RDS in premature infants, we reviewed all aspects of our business with a view to conserving our cash and implemented a fundamental change in our business strategy. We no longer are planning to establish our own specialty pulmonary organization to commercialize our potential pediatric products in the United States. Rather, to secure capital and advance our KL₄ surfactant pipeline programs, we are now seeking strategic alliances in all markets, including the United States, to support our research and development programs and, if approved, to commercialize our products.

In addition, in April 2009, we implemented cost containment measures and reduced our workforce from 115 to 91 employees, focusing primarily on our commercial and corporate administrative groups. We continue to maintain our core capabilities to support development of our KL₄ surfactant technology, including quality, manufacturing and research and development resources. We incurred a charge of \$0.6 million in the second quarter of 2009 associated with staff reductions and the close-out of certain contractual arrangements, which is included within the appropriate line items on the Statements of Operations (\$0.4 million in general and administrative expenses and \$0.2 million in research and development expenses). As of December 31, 2009, payments totaling \$0.6 million had been made related to these items and \$29,000 was unpaid, as follows:

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

<i>(in thousands)</i>	Severance and Benefits Related	Termination of Commercial Programs	Total
Q2 2009 Charge	\$ 554	\$ 74	\$ 628
Payments / Adjustments	<u>(450)</u>	<u>--</u>	<u>(450)</u>
Liability as of June 30, 2009	\$ 104	\$ 74	\$ 178
Payments / Adjustments	<u>(97)</u>	<u>(4)</u>	<u>(101)</u>
Liability as of September 30, 2009	\$ 7	\$ 70	\$ 77
Payments / Adjustments	<u>(7)</u>	<u>(41)</u>	<u>(48)</u>
Liability as of December 31, 2009	<u>\$ -</u>	<u>\$ 29</u>	<u>\$ 29</u>

Note 15 – Commitments

Future payments due under contractual obligations at December 31, 2009 are as follows:

<i>(in thousands)</i>	2010	2011	2012	2013	2014	There- after	Total
Loan payable ⁽¹⁾	\$ 10,573	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 10,573
Equipment loan obligations ⁽¹⁾	722	152	85	85	85	70	1,199
Operating lease obligations	1,127	1,146	1,166	320	150	-	3,909
CEO Severance obligations	<u>1,211</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>1,211</u>
Total	<u>\$ 13,633</u>	<u>\$ 1,298</u>	<u>\$ 1,251</u>	<u>\$ 405</u>	<u>\$ 235</u>	<u>\$ 70</u>	<u>\$ 16,892</u>

⁽¹⁾ See, Note 9: "Debt"

Our operating leases consist primarily of facility leases for our operations in Pennsylvania and New Jersey.

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, analytical technical services, research and development, 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 approximately 21,000 square feet of space for our manufacturing facility in Totowa, New Jersey, at an annual rent of \$150,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires in December 2014, subject to the landlord's right, upon two years' prior notice, to terminate the lease early. This early termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, depending upon the timing of the notice, if we satisfy certain financial conditions, the landlord would be obligated to make early termination payments to us. At the present time, we understand that the master tenant continues to be active in the premises. The total aggregate payments over the term of the lease are \$1.4 million. In connection with our manufacturing operations in Totowa, New Jersey, we have 15 employees subject to a collective bargaining arrangement which expires on December 3, 2010. For a

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discussion of our manufacturing strategy, *see*, “Item 1 – Business – Business Operations – Manufacturing and Distribution,” in our Annual Report on Form 10-K.

Our lease for 5,600 square feet of office and analytical laboratory space in Doylestown, Pennsylvania was terminated effective July 31, 2008 and all activities at this location have been consolidated into our laboratory space in Warrington, Pennsylvania. Our lease for 16,800 square feet of office and laboratory space at our facility in Mountain View, California, expired without renewal or extension on June 30, 2008. In December 2007, we consolidated these activities into our laboratory space in Warrington, Pennsylvania.

Rent expense under all of these leases for the years ended December 31, 2009, 2008, and 2007 was \$1.1 million, \$1.2 million and \$1.5 million, respectively.

In addition to the contractual obligations above, we have certain milestone and royalty payment obligations to Johnson & Johnson related to our product licenses. To date, of the \$2,500,000 aggregate potential amount of such milestone payments, we have paid \$450,000 for milestones that have been achieved.

Former CEO Commitment

Effective August 13, 2009, Dr. Robert J. Capetola resigned his positions as our President and Chief Executive Officer and as a member of our Board. We entered into a separation agreement and general release (Separation Agreement) with Dr. Capetola providing for (i) an upfront severance payment of \$250,000, and (ii) periodic payments in an amount equal to his base salary (calculated at a rate of \$490,000 per annum), in accordance with our payroll practices and less required withholdings. The periodic payments will end the earlier of (x) May 3, 2010 or (y) the date, if ever, that a Corporate Transaction (as defined below) occurs. In addition, Dr. Capetola will be entitled to (A) continuation of medical benefits and insurance coverage for a period of 24 or 27 months, depending upon circumstances, and (B) accelerated vesting of all outstanding restricted shares and options, which shall remain exercisable to the end of their stated terms.

The Separation Agreement provides further that, upon the occurrence of a Corporate Transaction prior to May 4, 2010, Dr. Capetola will receive a payment of up to \$1,580,000 (Additional Severance) or, if any such Corporate Transaction also constitutes a Change of Control (as such term is defined in the Separation Agreement), a payment of up to \$1,777,500; provided, however, that, in each case, any such payment will be reduced by the sum of the amounts described in clauses (i) and (ii) of this paragraph that theretofore have been paid. A “Corporate Transaction” is defined in the Separation Agreement as (1) one or more corporate partnering or strategic alliance transactions, Business Combinations or public or private financings that (A) are completed during the Severance Period (as defined in the Separation Agreement) and (B) result in cash proceeds (net of transaction costs) to the Company of at least \$20 million received during the Severance Period or within 90 calendar days thereafter, or (2) an acquisition of the Company, by business combination or other similar transaction, that occurs during the Severance Period and the consideration paid to stockholders of the Company, in cash or securities, is at least \$20 million. For this purpose, net proceeds will be calculated without taking into account any amounts received by the Company as reimbursement for costs of development and research activities to be performed in connection with any such transaction. *See also*, Note 18 – Subsequent Events.

Note 16 – Litigation

We are not aware of any pending or threatened legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

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Note 17 – Income Taxes

Since our inception, we have never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to our recorded tax benefit for the years ended December 31, 2009, 2008 and 2007 is as follows:

<i>(in thousands)</i>	December 31,		
	2009	2008	2007
	(As restated)		
Income tax benefit, statutory rates	\$ 10,156	\$ 13,296	\$ 13,601
State taxes on income, net of Federal benefit	423	2,102	2,363
Research and development tax credit	756	1,026	960
Employee Related	(1,471)	(1,306)	(1,118)
Other	107	(32)	(24)
Income tax benefit	9,971	15,086	15,782
Valuation allowance	(9,971)	(15,086)	(15,782)
Income tax benefit	\$ —	\$ —	\$ —

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2009 and 2008, are as follows:

<i>(in thousands)</i>	December 31,	
	2009	2008
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	\$ 126,291	\$ 115,401
Research and development tax credits	7,893	7,137
Compensation expense on stock	4,730	4,334
Charitable contribution carryforward	6	6
Other accrued	1,635	2,073
Depreciation	2,341	2,494
Capitalized research and development	2,069	2,411
Total long-term deferred tax assets	144,965	133,857
Long-term deferred tax liabilities	—	—
Net deferred tax assets	144,632	133,857
Less: valuation allowance	(144,965)	(133,857)
Deferred tax assets, net of valuation allowance	\$ —	\$ —

We are in a net deferred tax asset position at December 31, 2009 and 2008 before the consideration of a valuation allowance. Due to the fact that we have never realized a profit, management has fully reserved the net deferred tax asset since realization is not assured.

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At December 31, 2009 and 2008, we had available carryforward net operating losses for Federal tax purposes of \$315.5 million and \$292.6 million, respectively, and a research and development tax credit carryforward of \$7.9 million and \$7.1 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2028. Approximately \$11.9 million of the \$315.5 net operating loss carryforwards expire prior to 2013.

At December 31, 2009, we had available carryforward Federal and state net operating losses of \$1.8 million and \$16,000, respectively, related to stock based compensation. Additionally, at December 31, 2008 and 2007, we had available carryforward losses of approximately \$271.1 million and \$250.2 million, respectively, for state tax purposes. Of the \$271.1 state tax carryforward losses, \$246.7 million is associated with the state of Pennsylvania, with the remainder associated with New Jersey, California and Florida.

Utilization of net operating loss (NOL) and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOLs and credits. A full valuation allowance has been provided against our research and development credits and, if a future assessment requires an adjustment, an adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

Federal and state net operating losses, \$1.8 million and \$16,000, respectively, relate to stock-based compensation, the tax effect of which will result in a credit to equity as opposed to income tax expense, to the extent these losses are utilized in the future.

On January 1, 2007, we adopted the provisions of Accounting Standards Codification (ASC) Topic 740, *Accounting for Income Taxes*. Topic 740 creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The provisions of Topic 740 apply to all material tax positions in all taxing jurisdictions for all open tax years. The adoption of Topic 740 did not have a material effect on the Company's financial condition or results of operations for the year ended December 31, 2009.

Note 18 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2009 and 2008. The operating results for any quarter are not necessarily indicative of results for any future period. The quarterly financial information as of and for the quarters ended June 30, 2009, September 30, 2009 and December 31, 2009 have been restated to give effect to the matter discussed in Note 2.

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2009 Quarters Ended:

(in thousands, except per share data)

	<u>Mar. 31</u>	<u>June 30</u>	<u>Sept. 30</u>	<u>Dec. 31</u>	<u>Total Year</u>
		(As Restated)	(As Restated)	(As Restated)	(As Restated)
Revenues	\$ —	\$ —	\$ —	\$ —	\$ —
Expenses:					
Research and development	5,607	5,052	4,530	3,888	19,077
General and administrative	3,096	2,592	2,417	2,015	10,120
Total expenses	<u>8,703</u>	<u>7,644</u>	<u>6,947</u>	<u>5,903</u>	<u>29,197</u>
Operating loss	(8,703)	(7,644)	(6,947)	(5,903)	(29,197)
Change in fair value of common stock warrant liability	-	(1,323)	(1,662)	3,354	369
Other expense, net	(297)	(264)	(244)	(238)	(1,043)
Net loss	<u>\$ (9,000)</u>	<u>\$ (9,231)</u>	<u>\$ (8,853)</u>	<u>\$ (2,787)</u>	<u>\$ (29,871)</u>
Net loss per common share - basic and diluted	\$ (0.09)	\$ (0.08)	\$ (0.07)	\$ (0.02)	\$ (0.26)
Weighted average number of common shares outstanding	102,093	112,712	119,993	125,638	115,200

2009 Quarters Ended:

(in thousands)

	<u>Mar. 31</u>	<u>June 30</u>	<u>Sept. 30</u>	<u>Dec. 31</u>
		(As Restated)	(As Restated)	(As Restated)
Total Assets	\$ 26,271	\$ 29,940	\$ 23,809	\$ 21,403
Current Liabilities	\$ 8,844	\$ 22,437	\$ 23,488	\$ 18,989
Total Liabilities	\$ 20,832	\$ 23,864	\$ 24,730	\$ 20,107
Stockholders' Equity	\$ 5,439	\$ 6,076	\$ (921)	\$ 1,296

2008 Quarters Ended:

(in thousands, except per share data)

	<u>Mar. 31</u>	<u>June 30</u>	<u>Sept. 30</u>	<u>Dec. 31</u>	<u>Total Year</u>
Revenues	\$ 2,050	\$ 2,500	\$ 50	\$ —	\$ 4,600
Expenses:					
Research and development	7,232	7,439	6,724	5,170	26,566
General and administrative	4,505	5,076	3,726	3,121	16,428
Total expenses	<u>11,737</u>	<u>12,515</u>	<u>10,450</u>	<u>8,291</u>	<u>42,994</u>
Operating loss	(9,687)	(10,015)	(10,400)	(8,291)	(38,394)
Other expense, net	(27)	(200)	(239)	(246)	(712)
Net loss	<u>\$ (9,714)</u>	<u>\$ (10,215)</u>	<u>\$ (10,639)</u>	<u>\$ (8,537)</u>	<u>\$ (39,106)</u>
Net loss per common share - basic and diluted	\$ (0.10)	\$ (0.11)	\$ (0.11)	\$ (0.08)	\$ (0.40)
Weighted average number of common shares outstanding	96,649	96,691	98,619	100,474	98,116

Note 19 – Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2009 up through the date we issued these financial statements. During this period we did not have any material recognized subsequent events, however, there were three nonrecognized subsequent events described below:

In February 2010, we completed a public offering of 27,500,000 shares of our common stock and warrants to purchase 13,750,000 shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a public offering price of \$0.60 per unit, resulting in gross and net proceeds to us of \$16.5 million and \$15.1 million, respectively. *See*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements, for a further discussion of this offering.

With respect to our Former CEO Commitment (*see*, Note 14 – Commitments – Former CEO Commitment), since August 13, 2009, we have raised approximately \$5.89 million in gross proceeds utilizing our CEFFs (*see*, Note 10 – Stockholders' Equity – Committed Equity Financing Facilities – CEFF Financings). In addition, on February 23, 2010, we completed a public offering that resulted in net proceeds to us of approximately \$15.1 million (*see*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements). As the receipt from financings of more than \$20 million qualifies as a Corporate Transaction, our obligation under the Separation Agreement to make payment to Dr. Capetola of the Additional Severance has matured. Therefore, in accordance with the Separation Agreement, on March 5, 2010, we made a payment to Dr. Capetola in the amount of approximately \$1.06 million (less withholding), representing his Additional Severance payment, reduced by the payments previously made to him under the Severance Agreement, which total approximately \$0.52 million. Our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due at this time.

On February 16, 2010, we announced that we had received written guidance from the FDA advising us that, since an acceptable animal model (preterm lamb) of RDS already exists, a PD clinical trial approach would not be appropriate. We had previously expected, based on prior guidance received from the FDA, that a limited, pharmacodynamic-based (PD) clinical trial in preterm infants would be required to address the sole remaining CMC issue relating to the BAT that must be addressed to obtain approval of Surfaxin for the prevention of RDS in premature infants. As a result, instead of pursuing a limited clinical trial, we are now focused on completing the optimization and revalidation of the BAT and developing a comprehensive preclinical plan intended to meet the FDA's requirements. If these studies are successful, we believe that we could be in a position to file a Complete Response to the April 2009 Complete Response Letter in the first quarter of 2011, which could lead to approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in 2011.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-86105, Form S-3 No. 333-35206, Form S-3 No. 333-72614, Form S-3 No. 333-82596, Form S-3 No. 333-101666, Form S-3 No. 333-107836, Form S-3 No. 333-111360, Form S-3 No. 333-118595, Form S-3 No. 333-121297, Form S-3 No. 333-122887, Form S-3 No. 333-128929, Form S-3 No. 333-133786, Form S-3 No. 333-139173, Form S-3 No. 333-151536, Form S-3 No. 333-151654, and Form S-3 No. 333-156237) of Discovery Laboratories, Inc. and in related Prospectuses,

(2) Registration Statement (Form S-8 No. 333-148028) pertaining to the Discovery Laboratories, Inc. 2007 Long-Term Incentive Plan,

(3) Registration Statement (Form S-8 No. 333-33900, Form S-8 No. 333-55900, Form S-8 No. 333-67422, Form S-8 No. 333-100824, Form S-8 No. 333-109274, Form S-8 No. 333-116268, Form S-8 No. 333-127790, and Form S-8 No. 333-138476) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Discovery Laboratories, Inc.,

(4) Registration Statement (Form S-8 No. 333-59945) pertaining to the Amended and Restated 1998 Stock Incentive Plan of Discovery Laboratories, Inc., Discovery Laboratories, Inc. 1996 Stock Option/Stock Issuance Plan and Acute Therapeutics, Inc. 1996 Stock Option/ Stock Issuance Plan,

(5) Registration Statement (Form S-8 No. 333-37975) pertaining to the Restated 1993 Stock Option Plan of Ansan Pharmaceuticals, Inc. and the 1995 Stock Option Plan of Ansan Pharmaceuticals, Inc., and

(6) Registration Statement (Form S-8 No. 333-110412, Form S-8 No. 333-137643, Form S-8 No. 333-156443, Form S-8 No. 333-164470, Form S-8 No. 333-165809, and Form S-8 No. 333-169662) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our report dated March 10, 2010, except for Note 2, Note 4, and Note 5, as to which the date is November 12, 2010 with respect to the consolidated financial statements of Discovery Laboratories, Inc. and subsidiary and of our report dated March 10, 2010 except for the effects of the material weakness described in the sixth paragraph of that report, as to which the date is November 12, 2010, with respect to the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc. and subsidiary, included in this Annual Report (Form 10-K/A) of Discovery Laboratories, Inc. and subsidiary for the year ended December 31, 2009.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
November 12, 2010

CERTIFICATIONS

I, W. Thomas Amick, certify that:

1. I have reviewed this Amendment No. 2 on Form 10-K/A for the year ended December 31, 2009 of Discovery Laboratories, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2010

/s/ W. Thomas Amick
W. Thomas Amick
Chairman of the Board
and Chief Executive Officer

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Amendment No. 2 on Form 10-K/A for the year ended December 31, 2009 of Discovery Laboratories, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2010

/s/ John G. Cooper
John G. Cooper
President and Chief Financial Officer

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the “Company”) hereby certifies that our Amendment No. 2 on Form 10-K/A for the year ended December 31, 2009 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2010

/s/ W. Thomas Amick
W. Thomas Amick
Chairman of the Board
and Chief Executive Officer

/s/ John G. Cooper
John G. Cooper
President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

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