## SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## FORM 8-K

## CURRENT REPORT

## Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

July 29, 2009

Date of Report (Date of earliest event reported)

**Discovery Laboratories, Inc.** (Exact name of registrant as specified in its charter)

**000-26422** (Commission File Number) **94-3171943** (IRS Employer Identification Number)

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

(215) 488-9300

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Delaware** (State or other jurisdiction of incorporation)

## Item 2.02.

#### Results of Operations and Financial Condition.

On July 29, 2009, Discovery Laboratories, Inc. (the "Company") issued a press release announcing financial results for the quarter ended June 30, 2009. The press release is attached as Exhibit 99.1 hereto.

For the three and six months ended June 30, 2009, the Company reported a net loss of \$7.9 million (or \$0.07 per share) and \$16.9 million (or \$0.16 per share), respectively, on 112.7 and 107.4 million weighted average common shares outstanding, respectively. As of June 30, 2009, the Company had cash and marketable securities of \$23.4 million.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filings.

# Item 8.01. Other Events.

On July 29, 2009, the Company issued a press release and held a conference call reporting on the results of operations for the quarter ended June 30, 2009 and providing a status update on the Company's business strategy.

The Company anticipates that its cash outflow for the second half of 2009 will be approximately \$13 million, before taking into account any strategic alliances and or financing alternatives. In addition, as of June 30, 2009, the Company has a \$10.3 million loan with Novaquest, a strategic investment group of Quintiles Transnational Corp., which is due and payable on April 30, 2010. The Company is pursuing restructuring the terms of this loan with Novaquest and assessing alternative means of financing its payment; however, there can be no assurance that any such restructuring will occur or financing alternatives will be obtained.

Estimates of market size and business opportunities included in the press release are based in part on the Company's analysis of data derived from the following sources, among others: IMS Midas Data MAT, September 2008 (IMS Data); Vermont Oxford Network Data, 2005/2006 (VON Data); Soll, Cochrane Database of Systematic Reviews, 1997, Issue 4 (SC Data); CDC National Vital Statistics, 2005 (CDC NVS); UNICEF Online Data Set, 2005 (UNICEF Data); ZD Associates Primary Market Research, 2009 (ZDA Research); Gdovin, *J Peds Pharm & Therapuetics*, 2006 (PP&T). In addition, the Company's analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, economics and anticipated potential pharmaco-economic benefits of the Company's drug products, if approved.

Following receipt of a Complete Response Letter from the U.S. Food and Drug Administration in April 2009 with respect to Surfaxin for the prevention of Respiratory Distress Syndrome in premature infants, the Company has made fundamental changes in its business strategy. To secure capital and advance its KL<sub>4</sub> surfactant pipeline programs, the Company is seeking to reduce the financial burden on the Company by entering into strategic alliances in all markets, including, the United States. This change has resulted in an increase in interest among potential partners and the Company is now actively in discussions with certain interested parties. The Company seeks alliances that potentially provide non-dilutive capital in the form of upfront payments, milestone payments, commercialization royalties, a sharing of research and development expenses, and leveraging the expertise and capabilities of both parties. Although the Company is hopeful that it can achieve one or more strategic alliances in its key target markets or, in the alternative, obtain alternative financing to continue its operations, there can be no assurance that any such strategic alliance or financing will be achieved.

The Company believes that the current market for surfactants is underserved and constrained by limitations associated with the currently-approved animalderived surfactant products. The annual revenue from the current surfactant market is estimated to be approximately \$200 million worldwide (IMS Data); however, the Company does not believe that this revenue value is indicative of the RDS revenue opportunity that may be available to the Company. With its synthetic KL4 surfactant and capillary aerosolization technology platform, the Company plans to potentially displace the animal-derived surfactants and treat many more of the premature infants that currently are not treated with surfactant therapy today.

To avoid the risks associated with surfactant administration, which requires invasive intubation and mechanical ventilation, neonatologists prefer to treat RDSdiagnosed infants with nasal continuous positive air pressure (nCPAP). Approximately 240,000 low birth weight infants are managed on nCPAP in the U. S. annually (VON Data). nCPAP may fail in more than 50% (depending on gestational age) (VON Data) of these infants, who will require subsequent intubation and surfactant therapy, resulting in delayed surfactant therapy and potentially less favorable clinical outcomes (SC Data). As a result, of the more than 500,000 patients at-risk for developing RDS in developed markets worldwide, less than 200,000 are treated with surfactant therapy today, including approximately 80,000 in the United States (VON Data, CDC NVS, UNICEF Data).

Surfaxin LS<sup>™</sup>, a lyophilized (dry powder) formulation of Surfaxin, is administered in the same manner as Surfaxin and the currently-approved animal-derived surfactants. However, Surfaxin LS is handled more conveniently than both Surfaxin and the currently-approved animal-derived surfactants and exhibits characteristics that may further improve its clinical performance. The Company believes that the Surfaxin LS product profile may support a market penetration and a significant price premium relative to today's standard of care and could, over time, create a potential worldwide annual market opportunity of up to \$250 million.

Aerosurf<sup>®</sup> is a drug-device combination product that delivers the Company's  $KL_4$  surfactant in aerosolized form delivered via nCPAP. As nCPAP is the preferred method of treating RDS infants, Aerosurf, if approved, for the first time provides an opportunity to deliver surfactant therapy to many more premature infants, potentially significantly expanding the treated patient population. In addition, because Aerosurf has the potential to reduce the need for mechanical ventilation, which represents a significant hospital cost that can exceed \$25,000 per patient (ZDA Research, PP&T), the Company believes that it will be able to establish a new frame of reference for pricing and command a significant price premium for this novel product based on hospital cost savings (average days of mechanical ventilation avoided and reduction in related morbidities). As such, the Company believes that the potential Aerosurf product profile may, over time, support a potential worldwide annual RDS market opportunity approaching \$750 million.

As a result, the Company believes that the combined revenues from Surfaxin LS and Aerosurf have the potential to approach \$1 billion for the worldwide annual RDS market opportunity.

Surfaxin LS and Aerosurf are investigational drugs currently under development and are subject to all of the risks and uncertainties associated with development-stage drug product candidates, including whether regulatory development and marketing approvals can be successfully obtained. Examples of these and other risks and uncertainties are included in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

## Item 9.01. <u>Financial Statements and Exhibits</u>.

- (d) Exhibits
- 99.1 Press release dated July 29, 2009

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, market opportunities, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

# SIGNATURES

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

# **Discovery Laboratories, Inc.**

By: /s/ Robert J. Capetola

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

Date: August 3, 2009



# Discovery Labs Provides Second Quarter 2009 Financial Results and Business Strategy Update

Warrington, PA — July 29, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today is announcing financial results for the second quarter ended June 30, 2009 and is providing an update on its strategic business activities. The Company will host a conference call today at 10:00 AM EDT. The call-in number is 866-332-5218.

For the quarter ended June 30, 2009, the Company reported a net loss of \$7.9 million (or \$0.07 per share) on 112.7 million weighted average common shares outstanding compared to a net loss of \$10.2 million (or \$0.11 per share) on 96.7 million weighted average common shares outstanding for the same period in 2008. For the six months ended June 30, 2009, the Company reported a net loss of \$16.9 million (or \$0.16 per share) on 107.4 million weighted average common shares outstanding compared to a net loss of \$19.9 million (or \$0.21 per share) on 96.7 million weighted average common shares outstanding for the same period in 2008. Included in the net loss for the second quarter and six months ended June 30, 2009, is \$1.0 million and \$1.8 million, respectively, associated with stock based compensation under FASB Statement of Financial Accounting Standards No. 123(R) (FAS No. 123(R)).

As of June 30, 2009, the Company had cash and marketable securities of \$23.4 million, representing an increase of \$4.3 million over the previous quarter ended March 31, 2009, primarily due to the receipt of (i) net proceeds of \$10.5 million from the issuance in a registered direct public offering of 14.0 million shares of common stock and warrants to purchase 7 million shares, and (ii) aggregate proceeds of \$2.0 million from the issuance of 2.1 million shares of common stock pursuant to financings under the Company's Committed Equity Financing Facilities (CEFFs), offset by \$7.3 million used for operating activities and \$0.9 million used for debt service.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "We are developing our  $KL_4$  surfactant technology to improve respiratory critical care medicine. We believe our proprietary synthetic surfactant technology platform makes it possible, for the first time, to develop a significant pipeline of products to treat a wide range of respiratory diseases in pediatric and adult patient populations. Our top priority is to secure strategic alliance partners and access capital to advance our  $KL_4$  surfactant pipeline and maximize shareholder value. We are centering this initiative on our most advanced pipeline programs, Surfaxin LS<sup>TM</sup> and Aerosurf<sup>®</sup>, which have the potential to greatly improve the management of RDS.

The pharmacology of our  $KL_4$  surfactant technology was convincingly demonstrated in Surfaxin<sup>®</sup> Phase 3 clinical trials for the prevention of respiratory distress syndrome (RDS) in premature infants. We plan to leverage this established pharmacology and robust clinical experience to minimize development risk for Surfaxin LS and Aerosurf to treat patients with RDS. We believe that the RDS patient population is greatly underserved due to the inherent limitations of the current standard of care. Aerosurf is an aerosolized formulation of our  $KL_4$  surfactant that has the potential to reduce or eliminate invasive mechanical ventilation in a significant number of RDS infants. Aerosurf is intended to expand the availability of surfactant therapy to a much larger population of premature infants. We believe the successful development and commercialization of Surfaxin LS and Aerosurf have the potential, over time, to significantly expand the total RDS market from a current estimate of approximately \$200 million to a worldwide annual market opportunity approaching \$1 billion." The Company's KL<sub>4</sub> pipeline programs, which employ its synthetic KL<sub>4</sub> surfactant technology and Capillary Aerosolization Technology platform, are focused on the following respiratory disease targets:

- Respiratory Distress Syndrome RDS is one of the most common, potentially life-threatening disorders, with more than 500,000 low-birth-weight premature infants at risk globally each year. However today, fewer than 200,000 infants receive surfactant therapy (with animal-derived surfactants) because healthcare practitioners try to avoid the risks associated with intubation and mechanical ventilation which are presently required for surfactant administration. If the risk of intubation and mechanical ventilation could be reduced or eliminated, the surfactant-eligible RDS patient population could be significantly expanded. Discovery Labs advanced-staged RDS programs include:
  - Surfaxin LS is a lyophilized (dry powder) formulation of KL<sub>4</sub> surfactant that is reconstituted to a liquid immediately prior to administration. This formulation is intended to improve product flexibility and ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and exhibits characteristics that may further improve product clinical performance. To prepare for a Phase 2/3 clinical global registration program, the Company is planning to engage U.S. and European regulatory authorities this year. The Company intends to initiate a clinical program upon securing appropriate strategic alliances and necessary capital.
  - o Aerosurf is KL<sub>4</sub> surfactant in aerosolized form using the Company's proprietary Capillary Aerosolization Technology. Presently, surfactant treatment for neonatal RDS requires administration through an endotracheal tube and, although life-saving, the invasiveness of this method often results in serious respiratory conditions and complications. Aerosurf, if approved, holds the promise to significantly expand the use of KL<sub>4</sub> surfactant therapy by providing neonatologists with a novel means of administration without invasive endotracheal intubation and mechanical ventilation. The Company has met with and received guidance from the FDA with respect to the design of its planned Phase 2 clinical program. The Company intends to initiate a clinical program upon securing appropriate strategic alliances and necessary capital.
  - o Surfaxin, the Company's first  $KL_4$  surfactant product candidate, has demonstrated clinically meaningful survival and morbidity-lessening advantages versus animal-derived comparator surfactants (current standard of care). After receiving a Complete Response Letter from the FDA in April 2009, the Company plans to further engage the FDA to clearly understand the remaining requirements for Surfaxin approval; specifically, whether approval can be gained without conducting additional clinical trials. If the FDA requires additional clinical experience, the Company will assess whether such an investment would be prudent. The Company also plans on discussing with the FDA its continuing quality improvement initiatives intended to further optimize its fetal rabbit biological activity test (BAT), which serves as one of many analytical QC tests for Surfaxin and the Company's other  $KL_4$  pipeline programs. Depending upon the outcome of these interactions with the FDA, the Company will determine the ultimate path for Surfaxin including, if warranted, pursuing formal dispute resolution procedures.

- Acute Respiratory Failure (ARF)/Acute Lung Injury (ALI) ARF and ALI are severe respiratory conditions associated with prolonged critical care intervention, including mechanical ventilation. Both of these serious medical conditions entail severe surfactant dysfunction. No medications are currently approved for these debilitating conditions.
  - ARF typically occurs following a serious respiratory infection, such as influenza or respiratory syncytial virus (RSV). The Company is conducting a Phase 2 ARF clinical trial to determine whether Surfaxin improves lung function and reduces duration of mechanical ventilation in children diagnosed with ARF following a viral infection. Presently, enrollment is approximately 75% complete and the Company believes enrollment will be completed in the first quarter of 2010, with top-line results becoming available shortly thereafter.
  - o ALI is typically associated with severe respiratory infections, certain major surgeries, and lung injury including mechanical ventilator induced lung injury. The Company and a leading academic center are presently conducting a preclinical assessment to determine the potential utility of aerosolized KL<sub>4</sub> surfactant in the prevention and treatment of ALI.

Hospitalization for influenza and other viral infections, including the pandemic H1N1 virus, is associated with high mortality, morbidity and significant healthcare cost. The Company believes that its  $KL_4$  surfactant technology may provide a novel solution for patients that require critical care intervention following exposure to viral pathogens. The Company has met with U.S. Government officials to explore whether funding can be obtained to accelerate development of these programs in light of concerns regarding pandemic risk.

Cystic Fibrosis (CF) – CF is characterized by a genetic mutation that results in the production of thick, viscous mucus that is difficult to clear from the airways and typically leads to life-threatening respiratory infections. Preclinical and exploratory clinical studies suggest that therapeutic surfactants may improve lung function by loosening mucus and making it easier to clear. Aerosolized KL<sub>4</sub> surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in CF patients. The trial is being conducted at The University of North Carolina and is funded primarily through a grant provided by the Cystic Fibrosis Foundation. The trial has been designed to assess the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL<sub>4</sub> surfactant in CF patients. The results from this trial are anticipated in first quarter 2010.

## **Financial Information - Continued:**

The Company is actively assessing various strategic and financial alternatives to secure necessary capital and advance its  $KL_4$  respiratory pipeline programs to maximize shareholder value. The Company prefers to accomplish these objectives through strategic alliances. Although the Company is presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

Until any such strategic alliances or other financing alternatives are successfully secured, the Company has taken actions to conserve its financial resources by predominantly curtailing investments in its pipeline programs. The Company anticipates that its estimated cash outflow for the second half of 2009 will be approximately \$13 million, before taking into account any strategic alliances and or financing alternatives.

The Company currently has two CEFFs that (subject to certain conditions, including price and volume limitations) may allow the Company to raise additional capital to support its business plans. As of June 30, 2009, there were approximately 12.9 million shares (not to exceed an aggregate of \$23.0 million) available for issuance under the December 2008 CEFF, provided that the volume-weighted average price per share on each trading day in the draw-down period must be at least equal to the greater of \$0.60 or 90% of the closing market price on the trading day immediately preceding the draw-down period. Under the May 2008 CEFF, as of June 30, 2009, there were approximately 13.3 million shares (not to exceed an aggregate of \$52.3 million) available for issuance, provided that the average price on each trading day in the draw-down period must be at least equal to the greater of \$1.15 or 90% of the closing market price on the trading day immediately preceding the draw-down period.

As of June 30, 2009, the Company had \$10.3 million outstanding under its loan with Novaquest, a strategic investment group of Quintiles Transnational Corp. The outstanding principal and all accrued interest is due and payable on April 30, 2010. The Company is pursuing restructuring the terms of this loan with Novaquest and assessing alternative means of financing its payment; however, there can be no assurance that any such restructuring will occur or financing alternatives will be obtained.

Also, as of June 30, 2009, the company had \$1.4 million outstanding under its secured credit facility with GE Business Financial Services Inc., and \$0.5 million outstanding under the Machinery and Equipment Loan Fund with the Commonwealth of Pennsylvania Department of Community and Economic Development (MELF). Of this \$1.9 million outstanding debt, \$1.2 million was classified as a current liability and \$0.7 million as a long-term liability. Debt service for the second quarter 2009 was \$0.9 million and is expected to decrease to \$0.7 million in the third quarter and \$0.2 million in the fourth quarter. After giving effect to planned principle payments, the loan balance outstanding with GE is expected to be \$0.8 million and \$0.6 million for the third and fourth quarters, respectively.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 to be filed with the Securities and Exchange Commission, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

## **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary  $KL_4$  Surfactant Technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary Capillary Aerosolization Technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized  $KL_4$  surfactant to the deep lung without the complications currently associated with liquid surfactant administration. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at <u>www.Discoverylabs.com</u>.

#### Forward Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements, including without limitation, any relating to the second half of the Company's fiscal year, are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties are: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination products that Discovery Labs may develop, including that: (i) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever, (ii) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (iii) changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; risks relating to Discovery Labs' research and development activities, including (a) time-consuming and expensive preclinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail, and (b) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; risks relating to Discovery Labs' ability to develop and manufacture drug products and capillary aerosolization systems for clinical studies, and, if approved, for commercialization of drug and combination drug-device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, its contract manufacturers or suppliers in manufacturing drug products, drug substances and capillary aerosolization systems on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; risks that (a) market conditions, the competitive landscape or otherwise, may make it difficult to launch and profitably sell products, (b) Discovery Labs may be unable to identify potential strategic partners or collaborators to market its products, if approved, in a timely manner, if at all, and (c) Discovery Labs' products will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; the risk that Discovery Labs or its strategic partners or collaborators will not be able to attract or maintain qualified personnel; the risk that Discovery Labs will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facilities, or that the share price at which Discovery Labs may access the facilities from time to time will not enable Discovery Labs to access the full dollar amount potentially available under the facilities; the risk that Discovery Labs will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that Discovery Labs may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect Discovery Labs; risks of legal proceedings, including securities actions and product liability claims; risks relating to reimbursement and health care reform; and other risks and uncertainties described in Discovery Labs' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

**Contact Information:** Lisa Caperelli, Investor Relations 215-488-9413

# **Condensed Consolidated Statement of Operations**

(in thousands, except per share data)

		Three Months Ended June 30, (unaudited)			Six Months Ended June 30, (unaudited)			
		2009		2008		2009		2008
Revenue	\$		\$	2,500	\$		\$	4,550
Operating expenses: <sup>(1)</sup>								
Research and development		5,052		7,439		10,659		14,670
General and administrative		2,592		5,076		5,688		9,582
Total expenses		7,644		12,515		16,347		24,252
Operating loss		(7,644)		(10,015)		(16,347)		(19,702)
				(200)				
Other income / (expense)	<u> </u>	(264)	-	(200)	-	(561)	-	(227)
Net loss	\$	(7,908)	\$	(10,215)	\$	(16,908)	\$	(19,929)
Net loss per common share	\$	(0.07)	\$	(0.11)	\$	(0.16)	\$	(0.21)
Weighted average number of common shares outstanding		112,712		96,691		107,433		96,670

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three and six months ended June 30, 2009, the charges associated with FAS 123(R) were \$1.0 million (\$0.3 million in R&D and \$0.7 million in G&A) and \$1.8 million (\$0.4 million in R&D and \$1.4 million in G&A), respectively. For the three and six months ended June 30, 2008, the charges associated with FAS 123(R) were \$1.2 million (\$0.4 million in R&D and \$0.8 million in G&A) and \$2.2 million (\$0.7 million in R&D and \$1.5 million in G&A), respectively.

## **Condensed Consolidated Balance Sheets**

(in thousands)

ASSETS	June 30, 2009 (unaudited)		December 31, 2008	
Current Assets:	(-	,		
Cash and marketable securities	\$	23,377	\$	24,792
Receivables, prepaid expenses and other current assets		247		625
Total Current Assets		23,624		25,417
Property and equipment, net		5,285		5,965
Restricted Cash		400		600
Other assets		631		907
Total Assets	\$	29,940	\$	32,889
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	1,850	\$	2,111
Accrued expenses		4,253		5,313
Loan payable, including accrued interest <sup>(2)</sup>		10,291		-
Equipment loan and other liabilities		1,160		2,442
Total Current Liabilities		17,714		9,866
Long-Term Liabilities:				
Loan payable, including accrued interest		-		10,128
Equipment loan and other liabilities		1,427		1,962
Total Liabilities		19,141		21,956
Stockholders' Equity		10,959		10,933
Total Liabilities and Stockholders' Equity	\$	29,940	\$	32,889

<sup>(2)</sup> The loan from NovaQuest is due and payable on April 30, 2010.