SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

☒ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2001

or

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

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of small business issuer as specified in its charter)

Delaware	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
350 South Main Street, Suite 307	**18901**
Doylestown, Pennsylvania	
(Address of principal executive offices)	(Zip Code)

Registrants' telephone number, including area code: **(215) 340-4699**

As of October 22, 2001, 24,753,138 shares of Common Stock, par value $.001 per share, were outstanding.

Transitional Small Business Disclosure Format: o Yes ☒ No

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

(a development stage company)

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Condensed Consolidated Balance Sheets

	September 30, 2001	December 31, 2000
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,136,000	$ 7,281,000
Available-for-sale marketable securities	7,990,000	11,587,000
Prepaid expenses and other current assets	150,000	149,000
Note receivable - current	2,000	--
Total current assets	11,278,000	19,017,000
Property and equipment, net of depreciation	671,000	697,000
Note receivable	198,000	--
Security deposits	21,000	3,000
	$ 12,168,000	$ 19,717,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 836,000	$ 2,382,000

Accounts payable and accrued expenses	$ 836,000	$ 1,551,000
Capitalized lease - current	18,000	17,000
Total current liabilities	854,000	2,399,000
Deferred revenue	258,000	851,000
Capitalized lease	17,000	31,000
Total liabilities	1,129,000	3,281,000
Stockholders' Equity:		
Common stock, $.001 par value; 35,000,000 authorized; 21,189,353 and 20,871,112 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively	21,000	21,000
Additional paid-in capital	62,200,000	60,891,000
Unearned portion of compensatory stock options	(292,000)	(347,000)
Deficit accumulated during the development stage	(50,923,000)	(43,989,000)
Treasury stock (at cost; 38,243 and 26,743 shares of common stock at September 30, 2001 and December 31, 2000, respectively)	(239,000)	(213,000)
Accumulated other comprehensive income	272,000	73,000
Total stockholders' equity	11,039,000	16,436,000
	$ 12,168,000	$ 19,717,000

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		May 18, 1993 (Inception) Through September 30,
	2001	2000	2001	2000	2001
Revenues:					
Interest, dividends, and realized gains (losses)	$ (61,000)	$ 283,000	$ 658,000	$ 601,000	$ 3,168,000
Research and development collaborative contracts	197,000	538,000	915,000	557,000	1,861,000
	136,000	821,000	1,573,000	1,158,000	5,029,000
Expenses:					
Write-off of acquired in-process research and development and supplies	--	--	--	--	13,508,000
Research and development	1,706,000	1,768,000	5,198,000	3,801,000	25,423,000
General and administrative	921,000	436,000	2,977,000	1,791,000	13,358,000
Compensatory stock options	27,000	921,000	329,000	2,368,000	2,986,000

Interest	1,000	1,000	3,000	4,000	21,000
Total expenses	2,655,000	3,126,000	8,507,000	7,964,000	55,296,000
	(2,519,000)	(2,305,000)	(6,934,000)	(6,806,000)	(50,267,000)
Minority interest in net loss of subsidiary	--	--	--	--	26,000
Net loss	$ (2,519,000)	$ (2,305,000)	$ (6,934,000)	$ (6,806,000)	$ (50,241,000)
Net loss per common share - basic and diluted	$(0.12)	$(0.10)	$(0.33)	$(0.37)	
Weighted average number of common shares outstanding - basic and diluted	21,188,000	20,837,000	21,045,000	18,120,000	

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,		May 18, 1993 (Inception) through September 30,
	2001	2000	2001
Cash flows from operating activities:			
Net loss	$ (6,934,000)	$ (6,806,000)	$ (50,241,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Write-off of licenses	--	--	683,000
Depreciation and amortization	135,000	89,000	474,000
Compensatory stock options	329,000	2,368,000	2,986,000
Expenses paid using treasury stock and common stock	35,000	84,000	197,000
Loss on sale of property	--	--	4,000
Changes in:			
Prepaid expenses, inventory and other current assets	(1,000)	(697,000)	456,000
Accounts payable and accrued expenses	(1,546,000)	556,000	703,000
Other assets	(18,000)	15,000	(21,000)
Proceeds from research and development collaborative agreements	--	--	1,641,000
Amortization of deferred revenue	(593,000)	--	(1,383,000)
Expenses paid on behalf of company	--	--	18,000
Employee stock compensation	--	--	42,000
Reduction of research and development supplies	--	--	(161,000)

Net cash used in operating activities	(8,593,000)	(4,391,000)	(31,094,000)
Cash flows from investing activities:			
Purchase of property and equipment	(109,000)	(893,000)	(1,603,000)
Proceeds from sale of property and equipment	--	--	575,000
Employee notes receivable	(200,000)	--	(200,000)
Acquisition of licenses	--	--	(711,000)
Purchase of marketable securities	(5,583,000)	(10,157,000)	(38,842,000)
Proceeds from sale or maturity of marketable securities	9,379,000	--	31,529,000
Net cash payments on merger	--	--	(1,670,000)
Net cash provided by (used in) investing activities	3,487,000	(11,050,000)	(10,922,000)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	1,000,000	21,472,000	45,311,000
Purchase of treasury stock	(26,000)	--	(121,000)
Principal payments under capital lease obligation	(13,000)	(12,000)	(38,000)
Net cash provided by financing activities	961,000	21,460,000	45,152,000
Net (decrease) increase in cash and cash equivalents	(4,145,000)	6,019,000	3,136,000
Cash and cash equivalents - beginning of period	7,281,000	3,547,000	--
Cash and cash equivalents - end of period	$ 3,136,000	$ 9,566,000	$ 3,136,000
Supplementary disclosure of cash flows information:			
Interest Paid:	$ 3,000	$ 4,000	$ 21,000
Noncash transactions:			
Accrued dividends on Series C preferred stock	$ --	$ 36,000	$ 682,000
Series C preferred stock dividends paid using common stock	--	--	204,000
Preferred Stock issued for inventory	--	--	575,000
Equipment acquired through capitalized lease	--	--	73,000
Unrealized gain on marketable securities	199,000	125,000	272,000

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1 - The Company and Basis of Presentation

The Company

Discovery Laboratories, Inc. (the "Company") was formed to license and develop pharmaceutical products to treat a variety of human diseases. The accompanying financial statements include the accounts of the Company and its wholly owned subsidiary, Acute Therapeutics, Inc. ("ATI"). ATI is presently inactive, and all intercompany balances and transactions have been eliminated.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-QSB. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the nine-month period ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2000.

The Company's activities since incorporation have primarily consisted of conducting research and development, performing business and financial planning and raising capital. Accordingly, the Company is considered to be in the development stage, and expects to incur increasing losses and

require additional financial resources to achieve commercialization of its products.

The Company also depends on third parties to conduct research on the Company's behalf through various research agreements. All of the Company's current products under development are subject to license agreements that will require the payment of future royalties.

Note 2 - Net Loss Per Share

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

Note 3 - Comprehensive Loss

Total comprehensive loss was $2,095,000 and $6,735,000 for the three and nine months ended September 30, 2001, and $2,136,000 and $6,681,000 for the three and nine months ended September 30, 2000, respectively.

Note 4 - Subsequent Event

In October 2001, the Company received approximately $7.7 million in gross proceeds in a private placement in which the Company sold units consisting of an aggregate of approximately 3.6 million shares of common stock, and investor warrants to purchase approximately 713,000 shares of common stock. The offering price per unit of $2.175 represented an "at market" price per common share based on the average of the daily closing bid price of the common stock for the five trading days immediately preceding the closing date of the offering plus a nominal price per warrant. The investor warrants are exercisable for five years from the date of issuance at an exercise price of $2.365 per share of common stock. The placement agents for this transaction were paid an aggregate of $393,690 and were granted warrants to purchase approximately 165,000 shares of common stock at $2.394 per share of common stock.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Plan of Operations

Since its inception, the Company has concentrated its efforts and resources on the development and commercialization of pharmaceutical products and technologies. The Company has been unprofitable since its inception and has incurred a cumulative net loss of approximately $50.2 million as of September 30, 2001. The Company expects to incur increasing operating losses over the next several years, primarily due to the expansion of its research and development programs, including clinical trials for some or all of its existing products and technologies and other products and technologies that it may acquire or develop. The Company's ability to achieve profitability depends upon, among other things, its ability to discover and develop products, obtain regulatory approval for its proposed products and enter into agreements for product development, manufacturing and commercialization. None of the Company's products currently generate revenue and the Company does not expect to achieve prod uct revenues for the foreseeable future. Moreover, there can be no assurance that the Company will ever achieve significant revenues or profitable operations from the sale of any of its products or technologies.

The Company is a development stage pharmaceutical company that is focused on developing compounds intended for use primarily in critical care hospital settings. The Company is developing its lead product candidate, Surfaxin® (lucinactant), for the treatment of various critical care respiratory conditions.

The Company anticipates that during the next 12 months it will conduct substantial research and development on its products. The primary focus will be on conducting the clinical trials for the SurfaxinÒ indications noted below and on preclinical research related to using various formulations of SurfaxinÒ as an aerosol therapeutic, as well as a platform respiratory drug delivery technology. The Company anticipates the near term acquisition of approximately $600,000 of equipment in order to optimize the manufacturing process for SurfaxinÒ and to scale up the manufacturing process to meet expanded clinical and commercial needs. Since January 1, 2001, the Company has hired eight additional personnel due to the expansion of its clinical development efforts regarding SurfaxinÒ .

SURFAXIN® (lucinactant)

Idiopathic Respiratory Distress Syndrome (IRDS) in premature infants

The Company has initiated two Phase 3 multinational clinical trials evaluating Surfaxin® for the prevention and treatment of IRDS. The Company considers one of these a landmark Phase 3 trial that is designed to demonstrate the superiority of Surfaxin®, the Company's humanized, synthesized, peptide-containing surfactant, over certain currently available surfactant therapies. Approximately 1,500 patients in North and South America as well as Europe will be enrolled in this Phase 3 trial. This pivotal trial is intended, if successful, to provide the basis for marketing authorization applications for Surfaxin® with the United States Food and Drug Administration (the "FDA") and worldwide regulatory authorities. The second Phase 3 trial is designed as a supportive trial and compares Surfaxin® to an approved product that is animal-derived. The Company expects to complete recruitment for these trials in mid-2002. Condi tioned upon the successful outcome of such trials, the Company has committed to provide Surfaxin® to certain, but limited, Latin American regions that participate in the studies at a significantly reduced cost for a period of up to 10 years following commercialization. The Company has previously been granted Orphan Drug Status for Surfaxin® from the FDA for IRDS.

Meconium Aspiration Syndrome (MAS) in full-term infants

The Company commenced enrollment of a pivotal Phase 3 trial in MAS in May of 2000. The Phase 3 trial is intended to enroll up to 200 MAS patients. Results of a Phase 2 clinical trial in MAS in full-term newborns showed an improvement in oxygenation parameters and a savings of approximately three days on mechanical ventilation with the use of SurfaxinÒ as compared to controls. An Orphan Products Development Grant awarded to the Company by the FDA's Office of Orphan Products Development is expected to contribute towards the cost of this Phase 3 trial. The Company has also received Fast Track designation for Surfaxin® from the FDA for MAS. The Company has previously been granted Orphan Drug Status for Surfaxin® from the FDA for MAS. In addition, Surfaxin® has been granted orphan product designation by the European Agency for the Evaluation of Medicinal Products (EMEA). Given the Company's belief in the importance of IRDS to the Company's present development plan, resources have been and may continue to be reallocated from the MAS program to the IRDS program, which could effectively delay the completion of this trial. Given the curren t circumstances, patient recruitment is expected to be completed in fourth quarter 2002.

Acute Respiratory Distress Syndrome/ Acute Lung Injury (ARDS/ALI)

In November 2000, the Company initiated a Phase 2B clinical trial for the treatment of ARDS. This Phase 2B trial is designed in two parts -- Part A is a dose ranging study and Part B will consist of select doses identified in Part A compared to standard of care. The Company has received Fast Track designation for Surfaxin® from the FDA for ARDS. The Company has previously been granted Orphan Drug Status for Surfaxin® from the FDA for ARDS.

SUPERVENT™ (tyloxapol)

Cystic Fibrosis (CF)

The Company began a Phase 2A clinical trial of SuperVent™ for the treatment of CF on August 4, 1999. Analysis of the data from this randomized, double-blind, placebo-controlled trial show that SuperVent™ significantly decreased the amount of Interleukin 8 (IL-8) in the sputum of treated patients as compared to controls. IL-8 is an important body chemical that causes the migration of inflammatory cells to the site of release. The Phase 2A clinical trial involved eight patients. An additional Phase 2 trial will likely be required prior to commencement of a Phase 3 trial. Previously, the Company completed a Phase 1 trial in 20 normal healthy volunteers and determined a dose (1.25% tyloxapol concentration) that did not produce significant adverse effects. Presently, the Company is evaluating whether to continue development of SuperVent™ and if so, how such development would be conducted.

Results of Operations

The Company's expenses increased from $7,964,000 in the nine months ended September 30, 2000, to $8,507,000 in the nine months ended September 30, 2001. The increase was primarily due to an increase in the Company's research and development activities and the related increased administrative costs associated with the addition of new employees. The Company's total comprehensive net loss slightly increased from $6,681,000 in the nine months ended September 30, 2000, to $6,735,000 in the nine months ended September 30, 2001. In addition, primarily due to the increase in the weighted average common shares outstanding during the first nine months of 2001, the Company's net loss per share decreased from $0.37 in 2000 to $0.33 in 2001.

Liquidity

At September 30, 2001, the Company had working capital of approximately $10.4 million. The decrease in working capital is a result of the use of cash and marketable securities related to the research and development activities as planned. The Company believes its current working capital is sufficient to meet its planned research and development activities through the fourth quarter of 2002.

The Company will be required to raise additional capital in order to meet its overall business objectives, and there can be no assurance that it will be successful in doing so or, in general, that the Company will be able to achieve its business objectives.

The Company's working capital requirements will depend upon numerous factors, including, without limitation, progress of the Company's research and development programs, preclinical and clinical testing, timing and cost of obtaining regulatory approvals, levels of resources that the Company devotes to the development of manufacturing and marketing capabilities, technological advances, status of competitors and the ability of the Company to establish collaborative arrangements with other organizations.

Safe Harbor Statement Under the Private Securities Litigation Act of 1996

Certain statements set forth in this report, including, without limitation, statements concerning the Company's research and development programs and clinical trials, the possibility of submitting regulatory filings for the Company's products under development, the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products, the research and development of particular compounds and technologies and the period of time for which the Company's existing resources will enable the Company to fund its operations, are forward-looking statements. All such statements involve significant risks and uncertainties. Actual results may differ materially from those contemplated in the forward looking statements as a result of risks and uncertainties, including but not limited to the following: the Company's ability to obtain substantial additional funds; the uncertainties inherent in the process of developing products of the kind being deve loped by the Company; the Company's ability to establish additional collaborative and licensing arrangements and the degree of success of the Company's collaboration partners; the Company's ability to obtain and maintain all necessary patents or licenses; the Company's ability to demonstrate the safety and efficacy of product candidates and to receive required regulatory approvals; the Company's ability to meet obligations and required milestones under its license agreement; the Company's ability to compete successfully against other products and to market products in a profitable manner; and other risks and uncertainties set forth in the Company's filings with the Securities and Exchange Commission.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 2. Change in Securities.

In October 2001, the Company received approximately $7.7 million in gross proceeds from a private placement in which the Company sold units consisting of an aggregate of approximately 3.6 million shares of common stock, and warrants ("Investor Warrants") to purchase approximately 713,000 shares of common stock. The private placement was conducted in accordance with the terms of Rule 506 promulgated under the Securities Act and was therefore exempt from registration under the Securities Act. In accordance with Rule 506, the private placement was limited to investors that represented to the Company, and the Company believed, were accredited investors as such term is defined in Section 501 promulgated under the Securities Act. The offering price per unit of $2.175 represented an "at market" price per common share based on the average of the daily closing bid price of the common stock for the five trading days immediately preceding the closing date of the private placement plus a nominal price per Investor Warrant. The Investor Warrants are exercisable for five years from the date of issuance at an exercise price of $2.365 per share of common stock (subject to adjustment in certain circumstances). In connection with this private placement, the placement agent, Jesup & Lamont Securities Corp. (the "Placement Agent"), received fees of $393,690 and the Company agreed to issue to the Placement Agent warrants ("Placement Warrants") to purchase approximately 165,000 shares of common stock at an exercise price of $2.394 per share of common stock (subject to adjustment in certain circumstances) and for a period of five years from their date of issuance. The Investor Warrants and the Placement Warrants are subject to redemption and mandatory exercise, respectively, at the Company's sole discretion, at any time after their issuance upon prior notice, provided that the average closing sales price for the common stock as reported by the NASDAQ SmallCa p Market exceeds 300% of the then current exercise price per share for such warrants on any 20 trading days during any 30 consecutive trading-day-period.

The Company currently intends to use the net proceeds of this private placement for research and development purposes, including preclinical and clinical studies, and general corporate purposes. Specifically, we plan to use such net proceeds, together with our current working capital, to

conduct the planned Phase 3 clinical trials in IRDS, pre-clinical aerosol work for next-generation SurfaxinÒ products and possibly a Phase 3 clinical trial for ARDS/ALI.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

None.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

None.

(b) Reports on Form 8-K:

None.

Signatures

In accordance with the requirements of the Exchange Act, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Discovery Laboratories, Inc.

(Registrant)

Date: November 13, 2001 /s/ Robert J. Capetola, Ph.D.

Robert J. Capetola, Ph.D.

President/Chief Executive Officer

Date: November 13, 2001 /s/ Deni M. Zodda, Ph.D.

Deni M. Zodda, Ph.D.

Sr. Vice President, Business Development

(Principal Financial Officer)

Date: November 13, 2001 /s/ Cynthia Davis

Cynthia Davis

Controller
(Principal Accounting Officer)