SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-QSB

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

For the quarterly period ended March 31, 2001

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 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 Doylestown, Pennsylvania	18901
(Address of principal executive offices)	(Zip Code)

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

As of May 7, 2001, 21,173,383 shares of Common Stock, par value $.001 per share, were outstanding.

Transitional Small Business Disclosure Format: |_| Yes |X| No

DISCOVERY LABORATORIES, INC.

Table of Contents

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Condensed Consolidated Balance Sheets

	March 31, 2001 (Unaudited)	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 908,000	$ 7,281,000
Available-for-sale marketable securities	$ 14,894,000	11,587,000
Prepaid expenses and other current assets	378,000	149,000
Total current assets	16,180,000	19,017,000
Property and equipment, net of depreciation	703,000	697,000
Security deposits	3,000	3,000
	$ 16,886,000	$ 19,717,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,689,000	$ 2,382,000
Capitalized lease - current	18,000	17,000
Total current liabilities	1,707,000	2,399,000
Deferred revenue	653,000	851,000
Capitalized lease	24,000	31,000
Total liabilities	2,384,000	3,281,000
Stockholders' Equity:		
Common stock, $.001 par value; 35,000,000 authorized; 20,875,694 and 20,871,112 shares issued and outstanding at March 31, 2001 and December 31, 2000 respectively	21,000	21,000
Additional paid-in capital	60,896,000	60,891,000
Unearned portion of compensatory stock options	(274,000)	(347,000)
Deficit accumulated during the development stage	(46,049,000)	(43,989,000)
Treasury stock (at cost; 26,743 shares of common stock)	(213,000)	(213,000)
Accumulated other comprehensive income	121,000	73,000
Total stockholders' equity	14,502,000	16,436,000
	$ 16,886,000	$ 19,717,000

See notes to condensed consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,		May 18, 1993 (inception) through March 31,
	2001	2000	2001
Revenues:			
Interest, dividends, and realized gains	$ 302,000	$ 22,000	$ 2,812,000
Research and development collaborative contracts	456,000	19,000	1,402,000
	758,000	41,000	4,214,000
Expenses:			
Write-off of acquired in-process research and development and supplies			13,508,000
Research and development	1,664,000	774,000	21,889,000
General and administrative	1,080,000	735,000	11,461,000
Compensatory stock options	73,000	813,000	2,730,000
Interest	1,000	2,000	19,000
Total expenses	2,818,000	2,324,000	49,607,000
	(2,060,000)	(2,283,000)	(45,393,000)
Minority interest in net loss of subsidiary			26,000
Net loss	(2,060,000)	(2,283,000)	(45,367,000)
Net loss per common share - basic and diluted	$ (0.10)	$ (0.18)	
Weighted average number of common shares outstanding - basic and diluted	20,872,000	12,668,000	

See notes to condensed consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,		May 18, 1993 (Inception) through March 31,
	2001	2000	2001
Cash flows from operating activities:			
Net loss	$ (2,060,000)	$ (2,283,000)	$(45,367,000)
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	47,000	24,000	386,000
Compensatory stock options	73,000	813,000	2,730,000
Expenses paid using treasury stock and common stock	4,000	36,000	166,000
Loss on sale of property	--	--	4,000
Changes in:			
Prepaid expenses, inventory and other current assets	(229,000)	(56,000)	228,000
Accounts payable and accrued expenses	(693,000)	269,000	1,556,000
Other assets	--	--	(3,000)
Proceeds from research and development collaborative agreements	--	--	1,641,000
Amortization of deferred revenue	(198,000)	--	(988,000)
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	(3,056,000)	(1,197,000)	(25,557,000)
Cash flows from investing activities:			
Purchase of property and equipment	(53,000)	(45,000)	(1,547,000)
Proceeds from sale of property and equipment	--	--	575,000
Acquisition of licenses	--	--	(711,000)
Purchase of marketable securities	(3,259,000)	--	(36,518,000)
Proceeds from sale or maturity of marketable securities	--	--	22,150,000
Net cash payments on merger	--	--	(1,670,000)
Net cash used in investing activities	(3,312,000)	(45,000)	(17,721,000)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	1,000	21,290,000	44,312,000
Purchase of treasury stock	--	--	(95,000)
Principal payments under capital lease obligation	(6,000)	(4,000)	(31,000)
Net cash (used in) provided by financing activities	(5,000)	21,286,000	44,186,000
Net (decrease) increase in cash and cash equivalents	(6,373,000)	20,044,000	908,000
Cash and cash equivalents - beginning of period	7,281,000	3,547,000	--
Cash and cash equivalents - end of period	$ 908,000	$ 23,591,000	$ 908,000
Supplementary disclosure of cash flows information:			
Interest Paid:	$ 1,000	2,000	19,000
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	48,000	--	121,000

See notes to condensed consolidated financial statements

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 three-month period ended March 31, 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 2000 Annual Report on Form 10-KSB.

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 $2,012,000 and $2,283,000 for the three-month periods ending March 31, 2001 and 2000, respectively.

NOTE 4 - SUBSEQUENT EVENT

In April 2001, the Company received approximately $1 million in proceeds in a private placement sale of 296,560 shares of common stock to a limited partnership. This partnership may be deemed to be a related party, in that one of the partners is a member of the Company's board of directors. Such shares of common stock have not been registered under the Securities Act of 1933 (the "Act") and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Act. The investor is entitled to certain registration rights with respect to the resale of the shares of Common Stock issued in the offering.

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 $45.4 million as of March 31, 2001. The Company expects to incur significantly 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 revenues and the Company does not expect to achieve product 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(R) (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 the conduct of clinical trials for the Surfaxin(R) indications and on preclinical research related to using Surfaxin(R)-like formulations as an aerosol therapeutic, as well as a platform pulmonary drug delivery technology. The Company expects to continue the expansion of its research and development activities as a result of its receipt of approximately $17.5 million of net proceeds from its offering completed in March 2000. In continuation of its expanded research and development efforts, the Company anticipates the near term acquisition of approximately $600,000 of equipment in order to optimize the commercial process for Surfaxin(R) and to scale up the manufacturing process to meet expanded clinical and commercial needs. Since January 1, 2001, the Company has hired six additional personnel due to the expansion of its clinical development efforts regarding Surfaxin(R).

SURFAXIN(R) (lucinactant)

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 could 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 Surfaxin(R). An Orphan Products Development Grant awarded to the Company by the United States Food and Drug Administration (the "FDA") 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(R) from the FDA for MAS. The Company has previously been granted Orphan Drug Status for Surfaxin(R) from the FDA for MAS.

Idiopathic Respiratory Distress Syndrome (IRDS) in premature infants

The Company intends to initiate two Phase 3 multinational clinical trials in IRDS during the second quarter of 2001. The IRDS Phase 3 trials will use Surfaxin(R) versus active comparators that will be totally synthetic and/or animal-derived. The Phase 3 trials can be conducted at clinical sites located in North America, Europe and Latin America, and enrollment is expected to commence during the second quarter of 2001. Conditioned upon the successful outcome of such trials, the Company has committed to provide Surfaxin(R) 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. Such trials, and any other clinical trials of the Company's products in development that have not yet commenced, will require clearance by the FDA and/or other world health authorities. There can be no assurance as to the receipt or the timing of such clearance.

The Company has previously been granted Orphan Drug Status for Surfaxin(R) from the FDA for IRDS.

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. Enrollment is expected to commence during the second quarter of 2001. The Company has received Fast Track designation for Surfaxin(R) from the FDA for ARDS. The Company has previously been granted Orphan Drug Status for Surfaxin(R) from the FDA for ARDS.

SUPERVENT(TM) (tyloxapol)

Cystic Fibrosis (CF)

The Company began a Phase 2A clinical trial of SuperVent(TM) for the treatment of CF on August 4, 1999. Analysis of the data from this randomized, double-blind, placebo-controlled trial show that SuperVent(TM) significantly

decreased the amount of Interleukin 8 (IL-8) in the sputum of treated patients 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. In addition, the Company is establishing a development strategy for SuperVentTM to treat certain inflammatory respiratory diseases such as chronic bronchitis.

Results of Operations

The Company's expenses increased from $2,324,000 in the three months ended March 31, 2000, to $2,818,000 in the three months ended March 31, 2001. The increase was primarily due to an increase in the Company's research and development activities. The Company's total comprehensive net loss decreased from $2,283,000 in the three months ended March 31, 2000, to $2,012,000 in the three months ended March 31, 2001. In addition, primarily due to the increase in the weighted average common shares outstanding during the first three months of 2001, the Company's net loss per share decreased from $0.18 in 2000 to $0.10 in 2001.

Liquidity

At March 31, 2001, the Company had working capital of approximately $14.5 million. The Company believes its current working capital is sufficient to meet its planned research and development activities through the first quarter of 2002.

The Company will be required to raise additional capital in order to meet its 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, 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 developed 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.

None.

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:

1. A Form 8-K/A was filed with the Commission on January 8, 2001 and January 9, 2001. Both such amended current reports where amending a Form 8-K filed on December 22, 2000, that reported a change in the Company's certifying accountant.

2. A Form 8-K was filed with the Commission on March 2, 2001, reporting the Company's proposed plans to conduct a Phase 3 clinical trial of Surfaxin(R) in Latin America for the treatment of IRDS.

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: May 11, 2001

/s/ Robert J. Capetola, Ph.D.

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

Date: May 11, 2001

/s/ Deni M. Zodda, Ph.D.

Deni M. Zodda, Ph.D.
Sr. Vice President, Business Development
(Principal Financial Officer)

Date: May 11, 2001

/s/ Cynthia Davis

Cynthia Davis
Controller
(Principal Accounting Officer)