

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, 2000

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 November 13, 2000, 20,871,112 shares of Common Stock, par value \$.001 per share, were outstanding.

Transitional Small Business Disclosure Format: Yes No

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DISCOVERY LABORATORIES, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

Consolidated Balance Sheets

	September 30, 2000	December 31, 1999
	----- (Unaudited)	-----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,566,000	\$ 3,547,000
Marketable securities	\$ 10,282,000	
Inventory	575,000	575,000
Prepaid expenses and other current assets	763,000	66,000
	-----	-----
Total current assets	21,186,000	4,188,000
Property and equipment, net of depreciation	1,230,000	426,000
Security deposits	3,000	18,000
	-----	-----
	\$ 22,419,000	\$ 4,632,000
	-----	-----
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 981,000	\$ 425,000
Deferred revenue	1,036,000	1,036,000
Capitalized lease - current	15,000	15,000
	-----	-----
Total current liabilities	2,032,000	1,476,000
	-----	-----
Capitalized lease - noncurrent	36,000	48,000
	-----	-----
Stockholders' Equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized:		
Series B convertible; None and 1,530,756 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively	0	2,000
Series C redeemable convertible; None and 2,039 shares issued and outstanding at September 30, 2000 and December 31, 1999, respectively	0	2,481,000
Common stock, \$.001 par value; 35,000,000 authorized; 20,851,112 and 9,689,240 shares issued and outstanding at September 30, 2000 and December 31, 1999 respectively	21,000	10,000
Treasury stock (at cost; 26,743 and 2,000 shares of common stock at September 30, 2000 and December 31, 1999, respectively)	(213,000)	(5,000)
Additional paid-in capital	60,500,000	33,749,000
Unearned portion of compensatory stock options	(148,000)	(37,000)
Accumulated other comprehensive income	125,000	
Deficit accumulated during the development stage	(39,934,000)	(33,092,000)
	-----	-----
Total stockholders' equity	20,351,000	3,108,000
	-----	-----
	\$ 22,419,000	\$ 4,632,000
	=====	=====

See notes to financial statements

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

Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		May 18, 1993 (Inception) Through September 30, 2000
	2000	1999	2000	1999	2000
Interest	\$ 283,000	\$ 105,000	\$ 601,000	\$ 172,000	\$ 2,069,000
License Fees	(68,000)		(68,000)		
Research Grants and funding	606,000		625,000		762,000
	821,000	105,000	1,158,000	172,000	2,831,000
Expenses:					
Write-off of acquired in-process research and development and supplies					13,508,000
Research and development	1,768,000	449,000	3,801,000	2,340,000	16,670,000
General and administrative	436,000	378,000	1,791,000	1,700,000	9,404,000
Compensatory Stock Options	921,000		2,368,000		2,510,000
Interest	1,000		4,000		17,000
Total expenses	3,126,000	827,000	7,964,000	4,040,000	42,109,000
	(2,305,000)	(722,000)	(6,806,000)	(3,868,000)	(39,278,000)
Minority interest in net loss of subsidiary					26,000
Net loss	(2,305,000)	(722,000)	(6,806,000)	(3,868,000)	(39,252,000)
Other comprehensive income:					
Unrealized gain on marketable securities available for sale	169,000	(1,000)	125,000	(6,000)	125,000
Total comprehensive loss	\$ (2,136,000)	\$ (723,000)	\$ (6,681,000)	\$ (3,874,000)	\$ (39,127,000)
Net loss per share - basic and diluted	\$ (0.10)	\$ (0.09)	\$ (0.37)	\$ (0.49)	
Weighted average number of common shares outstanding	20,837,000	8,415,000	18,120,000	7,945,000	

See notes to financial statements

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

Consolidated Statements of Changes in Stockholders' Equity
January 1, 2000 through September 30, 2000

	Common Stock		Treasury Stock		Preferred Stock			
					Series B		Series C	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance - January 1, 2000	9,689,240	\$ 10,000	(2,000)	\$ (5,000)	1,530,756	\$ 2,000	2,039	\$2,481,000
Exercise of Stock Options	512,059		(31,743)	(245,000)				
Common placement warrant conversions	18,232							
Preferred placement warrant conversions	18,511							
Exercise of Class C & D Warrants	2,536,911	3,000						
Series B preferred stock conversions	4,765,631	5,000			(1,530,756)	(2,000)		
Dividend Payable on Series C preferred stock								36,000
Series C preferred stock conversions	398,186						(2,039)	(2,517,000)
Compensation charge on vesting/exercisability of stock option								
Compensatory stock options granted								
Common stock issued in payment for services	9,496							
Issuance of private placement units	2,902,846	3,000						
Unrealized gain on marketable securities available for sale								
Treasury Stock Issues in payment for services			7,000	\$ 37,000				
Net Loss								
Balance - September 30, 2000	20,851,112	\$ 21,000	(26,743)	\$(213,000)	--	--	--	--

	Additional Paid-In Capital	Unearned Portion of Compensatory Stock Options	Deficit Accumulated during Development Stage	Accumulated Other Comprehensive Income	Total
Balance - January 1, 2000	\$33,749,000	\$ (37,000)	\$(33,092,000)	\$ --	\$ 3,108,000
Exercise of Stock Options	480,000				235,000
Common placement warrant conversions					--
Preferred placement warrant conversions					--
Exercise of Class C & D Warrants	3,790,000				3,793,000
Series B preferred stock conversions	(3,000)				--
Dividend Payable on Series C preferred stock			(36,000)		--
Series C preferred stock conversions	2,517,000				--
Compensation charge on vesting/exercisability of stock option	2,136,000				2,136,000
Compensatory stock options granted	343,000	(111,000)			232,000
Common stock issued in payment for services	47,000				47,000
Issuance of private placement units	17,441,000				17,444,000
Unrealized gain on marketable securities available for sale				125,000	125,000
Treasury Stock Issues in payment for services					37,000
Net Loss			(6,806,000)		(6,806,000)
Balance - September 30, 2000	\$60,500,000	\$(148,000)	\$(39,934,000)	\$ 125,000	\$ 20,351,000

See notes to financial statements

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

Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,		May 18, 1993 (Inception) Through September 30,
	2000	1999	2000
	-----	-----	-----
Cash flows from operating activities:			
Net loss	\$ (6,806,000)	\$(3,868,000)	\$(39,252,000)
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	89,000	60,000	305,000
Compensatory stock options	2,368,000	124,000	2,510,000
Expenses paid using treasury stock and common stock	84,000		162,000
Changes in:			
Prepaid expenses and other current assets	(697,000)	137,000	(732,000)
Accounts payable and accrued expenses	556,000	(473,000)	848,000
Deferred revenue			1,036,000
Other assets	15,000		(3,000)
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	(4,391,000)	(4,020,000)	(21,036,000)
	-----	-----	-----
Cash flows from investing activities:			
Purchase of furniture and equipment	(893,000)	(172,000)	(1,439,000)
Proceeds from disposal of furniture and equipment			25,000
Acquisition of licenses			(711,000)
Purchase of marketable securities	(10,157,000)	(1,000,000)	(31,902,000)
Proceeds from sale or maturity of investments		2,126,000	22,150,000
Net cash payments on merger			(1,670,000)
	-----	-----	-----
Net cash provided by (used in) investing activities	(11,050,000)	954,000	(13,547,000)
	-----	-----	-----
Cash flows from financing activities:			
Proceeds from private placements of units, net of expenses	17,444,000	3,273,000	40,166,000
Purchase of treasury stock		(5,000)	(95,000)
Principal payments under capital lease obligation	(12,000)		(22,000)
Collections on stock subscriptions and proceeds from conversion of stock options and warrants	4,028,000	12,000	4,100,000
	-----	-----	-----
Net cash (used in) provided by financing activities	21,460,000	3,280,000	44,149,000
	-----	-----	-----
Net (decrease) increase in cash and cash equivalents	6,019,000	214,000	9,566,000
Cash and cash equivalents - beginning of period	3,547,000	1,474,000	
	-----	-----	-----
Cash and cash equivalents - end of period	\$ 9,566,000	\$ 1,688,000	\$ 9,566,000
	-----	-----	-----
Supplementary disclosure of cash flows information:			
Interest Paid:	\$ 4,000		\$ 17,000
Noncash transactions:			
Accrued dividends on preferred stock	\$ 36,000	\$ 153,000	\$ 682,000
Common stock and treasury stock issued in payment for services	84,000	73,000	157,000
Preferred Stock issued for inventory			575,000
Treasury stock received on exercise of options	245,000		245,000
Equipment acquired through capitalized lease			73,000
Series C preferred stock dividends paid using common stock			204,000

See notes to financial statements

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.

The accompanying unaudited, consolidated, condensed financial statements have been prepared in accordance with generally accepted accounting principles 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 generally accepted accounting principles 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, 2000 are not necessarily indicative of the results that may be expected for the year ended December 31, 2000. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's 1999 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.

Net Loss Per Share

Net loss per share is computed based on the weighted average number of common shares outstanding for the periods and common shares issuable for little or no cash consideration. 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.

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 \$39.3 million as of September 30, 2000. 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 in critical care hospital settings. The Company is also developing its lead product candidate, Surfaxin(R), 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. 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 to expand its research and development activities as a result of its receipt of approximately \$17.4 million of net proceeds from its offering completed in March 2000. In anticipation of optimizing the commercial process for Surfaxin(R), the Company is considering the purchase of

additional equipment at a cost of approximately \$500,000. Since May 2000, the Company has hired approximately 10 additional personnel to expand the late stage clinical development of Surfaxin(R) and anticipates hiring additional personnel to further augment the development of Surfaxin(R) and SuperVent(TM).

In November, the Company established a satellite office in the United Kingdom to manage and oversee its European clinical research programs. In addition, the Company plans to expand its clinical trial capabilities in other parts of the world.

SURFAXIN(R) (lucinactant)

Meconium Aspiration Syndrome (MAS) in full-term infants

The Company recently initiated a pivotal Phase 3 trial in MAS. The trial intends to enroll 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 reducing the costs of this Phase 3 trial. The Company has 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.

Respiratory Distress Syndrome (RDS) in premature infants

The Company is currently planning to commence a Phase 3 clinical trial of Surfaxin(R) for the treatment of RDS in premature infants during fourth quarter of 2000. Such trial, 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 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 RDS.

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

A pivotal Phase 2/3 clinical trial of Surfaxin(R) for the treatment of ARDS was commenced in July 1998. This trial was stopped on January 27, 2000 due to the Company's cash position and so that a new Phase 2 ARDS/ALI trial could be commenced using a new, less viscous formulation of Surfaxin(R). A new Phase 2 trial is currently being planned, which the Company expects to commence during the fourth quarter of 2000. 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 shows 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 8 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.

DSC-103 (Vitamin D analog)

Postmenopausal Osteoporosis

On December 5, 1997 a Phase 1 clinical study of DSC-103 as a once-daily, orally administered drug for the treatment of postmenopausal osteoporosis in the United States was initiated. Part B of such trial was commenced on April 2, 1998 and was successfully completed on June 29, 1998. The Company has recently terminated its license of DSC-103 with the licensor.

Results of Operations

The Company's expenses increased from \$4,040,000 in the nine months ended September 30, 1999, to \$7,964,000 in the nine months ended September 30, 2000. The increase was primarily due to a compensation charge of \$2,368,000 recorded as a result of the grant of options and the vesting of certain milestone-based employee stock options (including 250,000 options whose vesting was accelerated by the Board of Directors) and an increase in the Company's research and development activities. The Company's total comprehensive net loss increased from \$3,874,000 in the nine months ended September 30, 1999, to \$6,681,000 in the nine months

ended September 30, 2000. In addition, due to the increase in the weighted average common shares outstanding during the first nine months of 2000, the Company's net loss per share decreased from \$0.49 in 1999 to \$0.37 in 2000.

Liquidity

At September 30, 2000, the Company had working capital of \$19.2 million. In March 2000, the Company completed a private placement from which it received net proceeds of approximately \$17.4 million. The Company believes it has sufficient resources 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.

In October 2000, the Company was awarded a \$1 million Fast-Track Small Business Innovative Research (SBIR) grant by the US National Institutes of Health (NIH) to develop Surfaxin(R) for asthma, drug delivery, and respiratory distress syndromes.

The Company has decided not to pursue its planned occupation of a building adjacent to its Doylestown, Pennsylvania headquarters that was originally intended for its expanded clinical research activities. The Company has, however, as a lower cost alternative, amended its existing lease agreement in September 2000 to include an additional approximately 4,000 square feet of space immediately adjacent to its offices. The Company sold the adjacent building on October 30, 2000, for approximately \$565,000 in cash. After taking into account transaction costs, the proceeds from the sale of the building approximated its purchase price.

Pursuant to its sublicense agreement with Laboratorios Dr. Esteve of Spain, one of Spain's leading pharmaceutical companies, the Company received approximately \$600,000 in cash in October 2000 in support of its research and development activities with respect to Surfaxin(R).

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits:

27.1 Financial Data Schedule.

(b) Reports on Form 8-K:

1. 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 14, 2000

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

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

Date: November 14, 2000

/s/ Evan Myriantopoulos

Evan Myriantopoulos
Vice President, Finance
(Principal Financial Officer)

Date: November 14, 2000

/s/ Cynthia Davis

Cynthia Davis
Controller
(Principal Accounting Officer)

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM 10-QSB AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

3-MOS

	DEC-31-2000	
	JUL-01-2000	
	SEP-30-2000	
		9,566,000
		10,282,000
		0
		0
		575,000
	21,186,000	
		1,512,000
		(282,000)
	22,419,000	
2,032,000		
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22,419,000	20,380,000	
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	3,125,000	
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	1,000	
	(2,305,000)	
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		0
		0
	(2,305,000)	
		(0.10)
		(0.10)