INTERNEURON PHARMACEUTICALS INC
Form 10-Q
February 14, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 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 No. 0-18728

INTERNEURON PHARMACEUTICALS, INC.
(exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	04-3047911 (I.R.S. Employer Identification Number)
One Ledgemont Center, 99 Hayden Avenue Lexington, Massachusetts (Address of principal executive offices)	02421 (Zip Code)

Registrant's telephone number, including area code (781) 861-8444

(Former name, former address and former fiscal year, if changed since last report): Not Applicable

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No ____

Indicate the number of shares outstanding of each of the issuer's class of common stock, as of the latest practicable date.

Class:	Outstanding at February 13, 2001:
Common Stock $.001 par value	42,780,492 shares

INTERNEURON PHARMACEUTICALS, INC.

INDEX TO FORM 10-Q

Item 1. Financial Statements

INTERNEURON PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(Amounts in thousands except share data)

	December 31, 2000
ASSETS	
Current assets:	
Cash and cash equivalents	$ 22,563
Marketable securities	8,893
Accounts receivable	360
Insurance claim receivable	9,716
Settlement deposit receivable	--
Prepaids and other current assets	1,022
Total current assets	42,554
Investment in Incara	1,024
Property and equipment, net	121
	$ 43,699
LIABILITIES	
Current liabilities:	

Accounts payable	$ --
Accrued expenses	14,815
Deferred revenue	3,000
Current portion of capital lease obligations	--
Total current liabilities	17,815
Minority interest	332
STOCKHOLDERS' EQUITY	
Preferred stock; $.001 par value, 5,000,000 shares authorized; Series B, 239,425 shares issued and outstanding at December 31 and September 30, 2000, respectively (liquidation preference at December 31, 2000 $3,034)	3,000
Series C, 5,000 shares issued and outstanding at December 31 and September 30, 2000, respectively (liquidation preference at December 31, 2000 $503)	500
Common stock; $.001 par value, 80,000,000 shares authorized; 42,780,492 shares issued and outstanding at December 31 and September 30, 2000, respectively	43
Additional paid-in capital	274,248
Accumulated deficit	(251,659)
Accumulated other comprehensive income	(580)
Total stockholders' equity	25,552
	$ 43,699

The accompanying notes are an integral part of these unaudited consolidated financial statements.

INTERNEURON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the three months ended December 31, 2000 and 1999
(Unaudited)
(Amounts in thousands except per share data)

	Three Months Ended December 31,	
	2000	1999
Revenues:		
Royalty revenue	$ 360	$ --
Contract and license fee revenue	--	23,751
Total revenues	360	23,751
Costs and expenses:		
Cost of revenues	72	2,050
Research and development	1,041	2,660
General and administrative	1,611	2,473
Total costs and expenses	2,724	7,183
Income (loss) from operations	(2,364)	16,568

Investment income, net	507	291
Net income (loss)	$ (1,857)	$ 16,859
Net income (loss) per common share:		
Basic	$ (0.04)	$ 0.40
Diluted	$ (0.04)	$ 0.39
Weighted average common shares outstanding:		
Basic	42,780	42,031
Diluted	42,780	43,345

The accompanying notes are an integral part of these unaudited consolidated financial statements.

INTERNEURON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the three months ended December 31, 2000 and 1999
(Unaudited)
(Amounts in thousands)

	Three months ended
	2000
Cash flows from operating activities:	
Net income (loss)	$ (1,857)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:	
Depreciation and amortization	28
Noncash compensation	246
Change in assets and liabilities:	
Accounts receivable	(360)
Insurance claim receivable	(1,281)
Settlement deposit receivable	1,757
Prepaid and other assets	88
Accounts payable	(122)
Deferred revenue	--
Accrued expenses and other liabilities	(798)
Net cash provided (used) by operating activities	(2,299)
Cash flows from investing activities:	
Capital expenditures	(3)
Purchases of marketable securities	(981)
Proceeds from maturities and sales of marketable securities	977
Net cash (used) by investing activities	(7)

Cash flows from financing activities:	
Principal payments of capital lease obligations	(2)
Net change in cash and cash equivalents	(2,308)
Cash and cash equivalents at beginning of period	24,871
Cash and cash equivalents at end of period	$ 22,563

The accompanying notes are an integral part of these unaudited consolidated financial statements.

INTERNEURON PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

The consolidated financial statements included herein have been prepared by Interneuron Pharmaceuticals, Inc. ("Interneuron" or the "Company") without audit, pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company. The unaudited consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Form 10-K for the fiscal year ended September 30, 2000.

Interneuron is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late-stage clinical development.

B. Basic and Diluted Income (Loss) Per Share

The following table sets forth the computation of basic and diluted income (loss) per common share:

	Three Months Ended December 31,	
	2000	1999
Numerator for basic and diluted income (loss) per share:		
Net income (loss)	$ (1,857,000)	$16,859,000
Denominator for basic income (loss) per share:		

Weighted average shares outstanding	42,780,000	42,031,000
Denominator for diluted income (loss) per share:		
Weighted average shares outstanding	42,780,000	42,031,000
Dilutive effect of:		
Shares issuable in connection with stock option plans	--	39,000
Shares issued or issuable in connection with restricted stock awards	--	653,000
Shares issuable in connection with convertible preferred stock	--	622,000
Weighted average shares outstanding - diluted	42,780,000	43,345,000
Net income (loss) per common share -		
Basic	$ (0.04)	$ 0.40
Diluted	$ (0.04)	$ 0.39

During the three month period ended December 31, 2000, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period, were as follows: (i) options to purchase 9,551,143 shares of Common Stock at prices ranging from $1.88 to $20.13 with expiration dates ranging up to August 14, 2010; and (ii) warrants to purchase 750,000 shares of Common Stock with exercise prices ranging from $5.00 to $10.00 and with expiration dates ranging up to July 17, 2006. Additionally, during the three month period ended December 31, 2000, securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 75,000 shares of Common Stock at an exercise price of $1.53 and with an expiration date of September 15, 2006; Series B and C preferred stock convertible into 622,222 shares of Common Stock; and (iii) unvested Restricted Stock Awards of 450,000 shares of Common Stock granted pursuant to the Company's 1997 Equity Incentive Plan.

During the three month period ended December 31, 1999, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period, were as follows: (i) options to purchase 6,405,084 shares of Common Stock at prices ranging from $3.13 to $20.13 with expiration dates ranging up to March 17, 2009; (ii) warrants to purchase 812,500 shares of Common Stock with exercise prices ranging from $5.00 to $12.77 and with expiration dates ranging up to July 17, 2006; and (iii) call options sold by the Company for 2,000,000 shares of Common Stock with an exercise price of $36.00 and expiration dates ranging to December 31, 1999.

C. Comprehensive Income (Loss)

Comprehensive income (loss) for the three month period ended December 31, 2000 and 1999, respectively, is as follows:

	Three Months Ended December 31,

	2000	1999
Net income (loss)	$(1,857,000)	$ 16,859,000
Change in unrealized net gain on marketable and equity securities	(594,000)	239,000
Comprehensive income (loss)	$(2,451,000)	$ 17,098,000

D. Withdrawal of Redux(TM), Legal Proceedings, and Related Contingencies

On September 15, 1997, the Company and American Home Products Corp. ("AHP") announced a market withdrawal of the weight loss medication Redux, which was launched in June 1996. Interneuron has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, many of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. Following the dismissal and the anticipated dismissal of Interneuron as a defendant in certain cases, the Company estimates that there will be approximately 2,200 active cases. The existence of such litigation, including the time and expenses associated with the litigation, may materially adversely affect the Company's business, including its ability to obtain sufficient financing to fund operations. Although the Company is unable to predict its expense, or the outcome of, any such litigation, such expense or outcome may materially adversely affect the Company's future business, results of operations and financial condition.

In connection with the market withdrawal of Redux, the Company recorded as of September 30, 1997 certain charges aggregating approximately $10,800,000. Total expenses relating to the market withdrawal of Redux may exceed these amounts, which are estimates and do not include provisions for liability, if any, arising out of Redux-related litigation or other related costs.

In October 2000, the U.S. District Court for the Eastern District of Pennsylvania (the "District Court") returned $1,757,000 to the Company from the initial payment the Company made to the District Court pursuant to a proposed settlement which was rejected by the District Court. The Company reflected this amount at September 30, 2000 as a receivable.

On November 23, 1999, the District Court preliminarily approved a proposed nationwide settlement of AHP's product liability litigation related to Redux and Pondimin. The Company is not a released party under this settlement.

In fiscal 1999, the Company's three product liability insurers filed actions against Les Laboratoires Servier ("Servier") and the Company in the District Court, pursuant to the federal interpleader statute. The aggregate limits of the three commercial excess insurance policies issued by the insurers to the Company is $40,000,000. The insurers alleged that the Company asserted claims against these policies, a substantial portion of which has been used in the Company's defense of the litigation, and Servier, as an additional insured under these policies, asserted its right to claim against these policies. The insurers deposited the available proceeds up to the limits of their policies (the "Deposited Funds"), which are subject to ongoing claims by the Company and Servier, into the registry of the District Court. In October 2000, the District

Court dismissed the interpleader actions and the Deposited Funds were subsequently returned to the insurance companies. In January 2001, the Company was reimbursed for litigation expenses previously paid by the Company.

Reflected in insurance claim receivable at December 31, 2000 of $9,716,000 is $8,143,000 which the Company paid through December 31, 2000 to the group of law firms defending the Company in the Redux-related product liability litigation and an additional $1,573,000 which the Company has accrued for services rendered by such law firms through December 31, 2000. In January 2001, the Company received an $8,419,000 payment of insurance claims. The Company currently intends to continue paying such fees and file claims for reimbursement from the insurance companies. The Company expects to be reimbursed for its ongoing insurance claims until the aggregate limits of its commercial excess insurance policies are paid.

In January 2000, the Company announced it has filed a complaint against AHP in the Superior Court of the Commonwealth of Massachusetts. The complaint seeks unspecified but substantial damages and attorneys' fees pursuant to common and statutory law for AHP's knowing and willful deceptive acts and practices, fraud and misrepresentations and breach of contract. The Company cannot predict its costs relative to this litigation or the duration or outcome of the proceedings.

E. Agreements

In January 2001, the Company exercised its option and entered into an agreement to license IP 501, an orally-administered anti-fibrotic purified phospholipid compound in Phase 3 development for the treatment and prevention of liver diseases, including alcohol and Hepatitis C-induced cirrhosis. In exchange for future milestone payments and royalties on net sales, the license agreement gives the Company rights to develop and commercialize IP 501 in the United States, Canada, Japan, Korea, and, under certain circumstances, Europe and other markets. The Company is responsible for all remaining clinical and regulatory development, manufacturing, and marketing of the compound.

Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations:

Statements in this Form 10-Q that are not statements or descriptions of historical facts are "forward- looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by the Company or its representatives include, without limitation, statements regarding the Redux-related litigation, the Company's ability to successfully develop, obtain regulatory approval for and commercialize any products, to enter into corporate collaborations or obtain sufficient additional capital to fund operations, and are based on a number of assumptions. The words "believe," "expect," "anticipate," "intend," "plan," "estimate" or other expressions which are predictions of or indicate future events and trends and do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under "Risk Factors" and elsewhere in, or incorporated by reference into, the Company's Form 10-K for its fiscal year ended September 30, 2000. These factors include, but are not limited to, risks

relating to the Redux-related litigation; uncertainties relating to clinical trials, regulatory approval and commercialization of the Company's products; the early stage of products under development; need for additional funds and corporate partners; history of operating losses and expectation of future losses; product liability; dependence on third parties for manufacturing and marketing; competition; government regulation; risks associated with contractual arrangements; limited patents and proprietary rights; dependence on key personnel; uncertainty regarding pharmaceutical pricing and reimbursement and other risks. The forward-looking statements represent the Company's judgment and expectations as of the date of this Report. The Company assumes no obligation to update any such forward-looking statements.

The following discussion should be read in conjunction with the Company's unaudited consolidated financial statements and notes thereto appearing elsewhere in this report and audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000. Unless the context indicates otherwise, "Interneuron" or the "Company" refer to Interneuron Pharmaceuticals, Inc.

General

Description of Company

Interneuron is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late-stage clinical development. The Company is currently developing or has certain rights to five compounds in clinical development: pagoclone for panic and generalized anxiety disorders, trospium for overactive bladder, IP 501 for cirrhosis of the liver, citicoline for ischemic stroke, and PRO 2000 for the prevention of sexually transmitted diseases and human immunodeficiency virus ("HIV") infection. In addition, the Company has other compounds in earlier stages of development, including PACAP (pituitary adenylate cyclase activating polypeptide) for respiratory disease, diabetes, stroke and other neurodegenerative diseases.

Pagoclone

In December 1999, the Company entered into an agreement with Pfizer, Inc. ("Pfizer") (the "Pfizer Agreement"), under which it licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone. Under the Pfizer Agreement, Pfizer is responsible for conducting and funding all further clinical development, regulatory review, manufacturing and marketing of pagoclone on a worldwide basis. Under the Company's agreement with Aventis, S.A. ("Aventis"), Aventis is entitled to receive a portion of certain of the payments to be received by the Company from Pfizer. In January 2001, the Company announced the initiation by Pfizer of Phase 2 testing of pagoclone for generalized anxiety disorder. In August 2000, Pfizer initiated Phase 3 testing of pagoclone for panic disorder.

Trospium

In November 1999, the Company obtained an exclusive U.S. license to trospium, a prescription drug product currently marketed as a treatment for overactive bladder in Europe. Based on conversations with the FDA, the Company intends to conduct a standardized electrocardiograpic safety study which is recommended by the FDA for drugs in the pharmacological class of trospium. Additionally, based upon those discussions with the FDA, the Company believes that, in combination with the existing efficacy and safety data on trospium, a

single, successful 300-400 patient Phase 3 trial will be necessary and sufficient for submission of an NDA. On December 12, 2000, the Company filed an Investigational New Drug Application for trospium and expects to conduct the safety study in the second quarter of fiscal 2001. Assuming positive results from this study, the Company expects to begin the Phase 3 trial in fiscal 2001.

IP 501

In January 2001, the Company exercised its option and entered into an agreement to license IP 501, an orally-administered anti-fibrotic purified phospholipid compound in Phase 3 development for the treatment and prevention of liver diseases, including alcohol and Hepatitis C-induced cirrhosis. In exchange for future milestone payments and royalties on net sales, the license agreement gives the Company rights to develop and commercialize IP 501 in the United States, Canada, Japan, Korea, and, under certain circumstances, Europe and other markets. The Company is responsible for all remaining clinical and regulatory development, manufacturing, and marketing of the compound.

IP 501 is currently being studied in an 800-patient Phase 3 clinical trial sponsored by the Veterans Administration. Data analysis being performed by the Veterans Administration is ongoing and the Company intends to announce the results of the trial when they become available to the Company. In January 2001, the Company announced the start of a 250-patient government-funded Phase 3 trial designed to evaluate the safety and effectiveness of IP 501 in treating patients with Hepatitis C-associated cirrhosis.

Citicoline

In December 1999, the Company entered into an agreement with Takeda Chemical Industries Ltd. ("Takeda") (the Takeda Agreement"), subsequently amended, under which the Company licensed to Takeda exclusive U.S. and Canadian commercialization rights to citicoline. In December 2000, Takeda notified the Company of its decision not to participate in the further development of citicoline, thereby terminating the Takeda Agreement. Therefore, the Company has reacquired all rights to this compound. The Company does not intend to further develop citicoline unless it is able to find another partner to participate in such development. Takeda has also indicated that it will exercise its option under the Takeda Agreement to negotiate a license of another one of the Company's compounds, excluding trospium. Takeda has the

right until April 1, 2001 to negotiate a license for a chosen compound and an additional six month period during which the Company may not offer the compound selected by Takeda to any other party on terms more favorable than those offered to Takeda without first re-offering such compound to Takeda on such new terms.

PRO 2000

In June 2000, the Company licensed exclusive, worldwide rights from HeavenlyDoor.com, Inc., formerly Procept, Inc., to develop and market PRO 2000, a candidate topical microbicide to prevent infection by HIV and other sexually transmitted pathogens. In October 2000, dosing and follow-up for a Phase 1/Phase 2 clinical trial of PRO 2000 was completed by the National Institutes of Health at sites in the U.S. and South Africa. No serious adverse events were reported, and a full analysis of the data is ongoing. Additional government funded clinical testing is planned for 2001.

Sarafem(TM)

In June 1997, the Company licensed to Eli Lilly and Company ("Lilly")

worldwide, exclusive rights to Interneuron's patent covering the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome. Lilly has received approval for fluoxetine to treat premenstrual dysphoric disorder and is marketing the drug under the trade name Sarafem. The agreement provides for milestone payments and royalties based on net sales in the United States. In January 2001, the Company received from Lilly a royalty payment of $360,000 for sales during the three month period ended September 30, 2000 and recorded this payment as royalty revenue in the three month period ended December 31, 2000. The maximum aggregate royalty payments to Interneuron in any calendar year ranges from three to five million dollars and are conditioned upon the achievement of net sales in the United States above an annually escalating baseline. Royalties to the Company will terminate at the end of the first two consecutive quarters in which 70% or less of total Prozac prescriptions are "dispensed as written." Based on a recent federal court of appeals ruling, Lilly's composition of matter patent on fluoxetine will expire in the summer of 2001. Lilly has appealed the decision. If Lilly's appeal is not successful, potential royalty payments to the Company under this agreement may expire in early 2002.

Redux

Product Liability Litigation: On September 15, 1997, the Company announced a market withdrawal of its first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by AHP, the Company's licensee, in June 1996. Since the withdrawal of Redux, Interneuron has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, some of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. To date, there have been no judgments against the Company, nor has Interneuron paid any amounts in settlement of any of these claims. Following the dismissal and the anticipated dismissal of Interneuron as a defendant in certain cases, the Company estimates that there will be approximately 2,200 active cases. See "Liquidity and Capital Resources - Analysis of Cash Flows" and "PART II. Item 1. Legal Proceedings."

Results of Operations

Total revenues decreased to $360,000 in the three month period ended December 31, 2000 from $23,751,000 in the three month period ended December 31, 1999. Fiscal 2001 revenue consisted of royalty revenue received from Lilly on sales of Sarafem and fiscal 2000 revenue consisted of $23,751,000 in contract and license fee revenue, $13,750,000 of which was received from Pfizer pursuant to the Pfizer Agreement and $10,000,000 from Takeda pursuant to the Takeda Agreement.

Cost of revenues of $72,000 in the three month period ended December 31, 2000 relates to the amount due to Massachusetts Institute of Technology for their portion of the Sarafem royalty revenue and cost of revenues of $2,050,000 in the three month period ended December 31, 1999 consists of $2,050,000 paid to Aventis for their portion of the initial payment received by the Company from Pfizer.

Research and development expense decreased $1,619,000, or 61%, to $1,041,000 in the three month period ended December 31, 2000 compared to $2,660,000 in the three month period ended December 31, 1999. This decrease was primarily due to the absence in fiscal 2001 of expenses relating to the citicoline Phase 3 trial which completed in January 2000 and reduced payroll and related costs due to employee reductions in fiscal 2000 partially offset by

development costs for two new products under development by the Company, trospium and PRO 2000.

General and administrative expense decreased $862,000, or 35%, to $1,611,000 in the three month period ended December 31, 2000 from $2,473,000 in the three month period ended December 31, 1999. This decrease was primarily due to reduced payroll and related costs due to the decrease in personnel and reduced facilities costs partially offset by increased legal fees relating to the Company's suit against AHP.

Investment income, net increased $216,000, or 74%, to $507,000 in the three month period ended December 31, 2000 from $291,000 in the three month period ended December 31, 1999. This increase is primarily due to higher average invested balances in the three month period ended December 31, 2000.

For the three month period ended December 31, 2000, the Company had a net loss of ($1,857,000), or ($0.04) per share, diluted, compared to net income of $16,859,000, or $0.39 per share, diluted, for the three month period ended December 31, 1999. This substantial change from net income to net loss is primarily the result of $23,750,000 of contract and license fee revenue from the Pfizer and Takeda Agreements recorded in the three month period ended December 31, 1999, partially offset by the royalty revenue from Lilly and reduced costs and expenses incurred in the three month period ended December 31, 2000. The Company expects to report losses for its consolidated operations in fiscal 2001.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At December 31, 2000, the Company had consolidated cash, cash equivalents and marketable securities of $31,456,000 compared to $33,751,000 at September 30, 2000. This decrease of $2,295,000 is primarily due to funding of the net loss of $1,857,000 and payments of approximately $1,925,000 to the group of law firms defending the Company in the Redux-related product liability litigation, which is included in insurance claim receivable, partially offset by the $1,757,000 settlement deposit collected by the Company. In January 2001, the Company received an $8,419,000 payment of insurance claims. See "Analysis of Cash Flows" and "Part II, Item 1. Legal Proceedings."

While the Company believes it has sufficient cash for currently planned expenditures through fiscal 2001 based on certain assumptions relating to operations and other factors, excluding any settlements of the Redux-related litigation by and against the Company, it will require additional funds after such time. The Company does not currently have sufficient funds to fully-develop and commercialize any of its current products and product candidates and will require additional funds or corporate collaborations for the development and commercialization of its compounds in development, as well as any new businesses, products or technologies acquired or developed in the future. The Company has no commitments or arrangements to obtain such funds. If such funds are not available, the Company will be required to further reduce its operations and delay development and regulatory efforts. As a result of the uncertainties and costs associated with the Redux-related litigation, including the fact that no settlement agreements exist or are pending and the stays of pending and future product liability litigation and claims against the Company have been vacated by the court, market conditions and other factors generally affecting the Company's ability to raise capital, there can be no assurance that the Company will be able to obtain additional financing to satisfy future cash requirements or that any financing will be available on terms favorable or acceptable, or at all.

Product Development

The Company expects to continue to expend substantial additional amounts for the development of its products and expects to increase expenditures for the development of trospium and PRO 2000 in the coming fiscal quarters. There can be no assurance that results of any on-going current or future pre-clinical or clinical trials will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with current Good Manufacturing Practices or successfully marketed in a timely manner, or at all, or that the Company will have sufficient funds to commercialize any of its products.

Analysis of Cash Flows

Cash used by operating activities during the three month period ended December 31, 2000 of $2,299,000 consisted primarily of a net loss of $1,857,000 and payments of $1,925,000 relating to the Company's temporary funding of Redux-related product liability defense costs (discussed below), partially offset by receipt of the $1,757,000 settlement deposit.

Reflected in insurance claim receivable at December 31, 2000 of $9,716,000 is $8,143,000 which the Company paid through December 31, 2000 to the group of law firms defending the Company in the Redux-related product liability litigation and an additional $1,573,000 which the Company owes to such law firms for services rendered through December 31, 2000 (see Part II, Item 1. Legal Proceedings). In January 2001, the Company received an $8,419,000 payment of insurance claims. The Company is currently paying these law firms' fees at the rate of approximately $2,000,000 per quarter and expects to be reimbursed for its ongoing insurance claims, until the maximum aggregate limits of the Company's commercial excess insurance policies are paid.

Other

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). SFAS No. 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives), and for hedging activities. SFAS No. 133 requires companies to recognize all derivatives as either assets or liabilities, with the instruments measured at fair value. The accounting for changes in fair value, gains or losses, depends on the intended use of the derivative and its resulting designation. In June 1999, the FASB issued SFAS No. 137 which deferred the effective date of adoption of SFAS No. 133 to fiscal years beginning after June 15, 2000. The Company adopted SFAS 133 in the fiscal quarter ended December 31, 2000 and the adoption did not have an impact on the Company's financial statements.

In December 1999, the SEC issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), which clarifies the SEC's views related to revenue recognition and disclosure. In June 2000, the SEC issued SAB 101B which delays the implementation date of SAB 101. The Company will adopt SAB 101 in the fourth quarter of fiscal 2001 and is presently determining the effect it will have on its financial statements.

PART II - Other Information

Item 1. Legal Proceedings

Product Liability Litigation: Subsequent to the market withdrawal of Redux in September 1997, the Company has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 legal actions, many of which purport to be class actions, in federal and state courts relating to the use of Redux. The actions generally have been brought by individuals in their own right or on behalf of putative classes of persons who claim to have suffered injury or who claim that they may suffer injury in the future due to use of one or more weight loss drugs including Pondimin (fenfluramine), phentermine and Redux. Plaintiffs' allegations of liability are based on various theories of recovery, including, but not limited to, product liability, strict liability, negligence, various breaches of warranty, conspiracy, fraud, misrepresentation and deceit. These lawsuits typically allege that the short or long-term use of Pondimin and/or Redux, independently or in combination (including the combination of Pondimin and phentermine popularly known as "fen-phen"), causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. In addition, some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of the individual or the class. In addition, some actions seeking class certification ask for certain types of purportedly equitable relief, including, but not limited to, declaratory judgments and the establishment of a research program or medical surveillance fund. On December 10, 1997, the federal Judicial Panel on Multidistrict Litigation issued an Order allowing for the transfer or potential transfer of the federal actions to the Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings. To date, there have been no judgments against the Company, nor has Interneuron paid any amounts in settlement of any of these claims. Following the dismissal and the anticipated dismissal of Interneuron as a defendant in certain cases, the Company estimates that there will be approximately 2,200 active cases.

Rejected Settlement: On September 27, 1999, the Company announced that the District Court rejected

a proposed agreement among the Company and the Plaintiffs Management Committee in the Multidistrict Litigation to settle all product liability litigation and claims against the Company related to Redux. The District Court found that the proposed settlement did not meet the requirements for limited fund class actions, as described by the Supreme Court in its June 23, 1999 decision in Ortiz v. Fibreboard Corp. The District Court also vacated the stays of pending and future litigation that were previously in effect. The Company filed a petition with the U.S. Court of Appeals for the Third Circuit on October 12, 1999, seeking review of the District Court's ruling and on April 13, 2000 moved to dismiss such petition. The motion was granted on April 25, 2000. As a result of the District Court's rejection of the proposed settlement agreement, the ongoing Redux-related litigation is proceeding against the Company.

On November 23, 1999, the District Court preliminarily approved a proposed nationwide settlement of AHP product liability litigation related to Redux and Pondimin. The Company is not a released party under this settlement.

Interpleader Litigation and Funding of Product Liability Litigation Costs: On November 20, 1998, December 30, 1998 and February 5, 1999, the Company's three product liability insurers filed actions against Servier and the Company in the District Court, pursuant to the federal interpleader statute. The aggregate limits of the three commercial excess insurance policies issued by the insurers to the Company is $40,000,000 in tiers of $20,000,000, $5,000,000 in excess of $20,000,000, and $15,000,000 in excess of $25,000,000. The insurers alleged that the Company asserted claims against these policies, a substantial portion of which has been used in the Company's defense of the litigation, and Servier, as an additional insured under these policies, asserted its right to claim against these policies. The insurers deposited the available proceeds up to the limits of their policies (the "Deposited Funds"), which are subject to ongoing claims by the Company and Servier, into the registry of the District Court. On May 3, 2000, the Company moved to dismiss such actions as moot in light of the District Court's rejection of the Company's proposed settlement and the dismissal of the Company's petition to appeal from such order. In October 2000, the District Court dismissed the interpleader actions and the Deposited Funds were subsequently returned to the insurance companies. In January 2001, the Company was reimbursed for litigation expenses previously incurred by the Company. See "Liquidity and Capital Resources--Analysis of Cash Flows."

Complaint Against AHP: On January 24, 2000, the Company announced it has filed a complaint against AHP in the Superior Court of the Commonwealth of Massachusetts. The complaint seeks unspecified but substantial damages and attorneys' fees pursuant to common and statutory law for AHP's knowing and willful deceptive acts and practices, fraud and misrepresentations and breach of contract. AHP filed an answer to such complaint. The Company cannot predict its costs relative to this litigation or the duration or the outcome of the proceedings.

General: Pursuant to agreements between the parties, under certain circumstances, the Company may be required to indemnify Servier, Boehringer Ingelheim Pharmaceuticals, Inc. and AHP, and the Company may be entitled to indemnification by AHP, against certain claims, damages or liabilities incurred in connection with Redux. The cross indemnification between the Company and AHP generally relates to the activities and responsibilities of each company.

Although the Company maintains certain product liability and director and officer liability insurance and intends to defend these and similar actions vigorously, the Company has been required and may continue to be required to devote significant management time and resources to these legal actions. In the absence of a settlement and in the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against the Company, the Company's business, financial condition and results of operations could be materially adversely affected. Even if a settlement is reached, the terms of such settlement may include cash and/or the issuance of the Company's securities, which may

materially adversely affect the Company's financial condition and results of operations and result in dilution to the Company's stockholders. The uncertainties and costs associated with these legal actions have had, and may continue to have, an adverse effect on the market price of the Company's Common Stock and on the Company's ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, or to obtain product liability insurance for other products at costs acceptable to the Company, or at all, any or all of which may materially adversely affect the Company's business, financial condition and results of operations.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.119 - License Agreement by and between Charles S. Lieber, M.D. and Interneuron Pharmaceuticals, Inc. dated December 26, 2000(1)

(1) Confidential treatment requested.

(b) Reports on Form 8-K

The Company did not file any reports on Form 8-K during the three month period ended December 31, 2000.

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 thereunto duly authorized.

INTERNEURON PHARMACEUTICALS, INC.

Date: February 14, 2001 By: /s/ Glenn L. Cooper

Glenn L. Cooper, M.D., President, Chairman and Chief Executive Officer (Principal Executive Officer)

Date: February 14, 2001 By: /s/ Michael W. Rogers

Michael W. Rogers, Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)

Date: February 14, 2001 By: /s/ Dale Ritter

Dale Ritter, Senior Vice President, Finance (Principal Accounting Officer)