

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

INTERNEURON PHARMACEUTICALS INC  
Form 10-Q  
February 14, 2002

UNITED STATES  
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, 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 No. 0-18728

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

-----  
Delaware 04-3047911  
(State or other jurisdiction of (I.R.S. Employer Identification  
incorporation or organization) Number)  
-----

One Ledgemont Center, 99 Hayden Avenue 02421-7966  
Lexington, Massachusetts (Zip Code)  
(Address of principal executive offices)  
-----

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 12, 2002:  
Common Stock \$.001 par value 46,506,682 shares

INTERNEURON PHARMACEUTICALS, INC.

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

INDEX TO FORM 10-Q

PART I. FINANCIAL INFORMATION	PAGE
Item 1. Financial Statements	
Consolidated Balance Sheets as of December 31, 2001 and September 30, 2001 .....	3
Consolidated Statements of Operations for the Three Months ended December 31, 2001 and 2000 .....	4
Consolidated Statements of Cash Flows for the Three Months ended December 31, 2001 and 2000 .....	5
Notes to Unaudited Consolidated Financial Statements .....	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations .....	8
Item 3. Quantitative and Qualitative Disclosures about Market Risk .....	12
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings .....	12
Item 6. Exhibits and Reports on Form 8-K .....	14
SIGNATURES .....	15

-2-

Item 1. Financial Statements

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

December 31,  
2001  
-----

ASSETS

Current assets:

Cash and cash equivalents	\$ 42,182
Marketable securities	4,571
Accounts receivable	3,527

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

Prepays and other current assets	459
	-----
Total current assets	50,739
Marketable securities	4,088
Equity securities	563
Property and equipment, net	41
Insurance claim receivable	1,258
	-----
Total assets	\$ 56,689
	=====
LIABILITIES	
Current liabilities:	
Accounts payable	\$ --
Accrued expenses	5,963
	-----
Total current liabilities	5,963
Minority interest	97
STOCKHOLDERS' EQUITY	
Preferred stock; \$.001 par value, 5,000,000 shares authorized;	
Series B, 239,425 shares issued and outstanding	
(liquidation preference at December 31, 2001 \$3,034)	3,000
Series C, 5,000 shares issued and outstanding	
(liquidation preference at December 31, 2001 \$503)	500
Common stock; \$.001 par value, 80,000,000 shares authorized;	
46,426,349 and 43,283,016 shares issued and outstanding at December 31	
and September 30, 2001, respectively	46
Additional paid-in capital	300,435
Accumulated deficit	(253,239)
Accumulated other comprehensive income (loss)	(113)
	-----
Total stockholders' equity	50,629
	-----
Total liabilities and stockholders' equity	\$ 56,689
	=====

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

-3-

INTERNEURON PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
For the three months ended December 31, 2001 and 2000  
(Unaudited)  
(Amounts in thousands except per share data)

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

	Three Months Ended De 2001
	-----
Revenues:	
Royalty revenue	\$ 3,199
Contract and license fee revenue	342
	-----
Total revenues	3,541
Costs and expenses:	
Cost of revenues	838
Research and development	3,245
General and administrative	1,578
	-----
Total costs and expenses	5,661
	-----
Loss from operations	(2,120)
Investment income, net	228
Minority interest	(54)
	-----
Loss before cumulative effect of change in accounting principle	(1,946)
Cumulative effect of change in accounting principle	--
	-----
Net loss	\$ (1,946)
	=====
Loss per common share- basic and diluted:	
Loss before cumulative effect of change in accounting principle	\$ (0.04)
Cumulative effect of change in accounting principle	--
Net loss	\$ (0.04)
Weighted average common shares outstanding:	
Basic and diluted	43,659
	=====

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

-4-

INTERNEURON PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
For the three months ended December 31, 2001 and 2000  
(Unaudited)  
(Amounts in thousands)

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

	Three months ended 2001 -----
Cash flows from operating activities:	
Net loss	\$ (1,946)
Adjustments to reconcile net loss to net cash used in operating activities:	
Cumulative effect of change in accounting principle	--
Depreciation and amortization	26
Minority interest in net income of consolidated subsidiary	54
Noncash compensation	604
Changes in assets and liabilities:	
Accounts receivable	(3,196)
Insurance claim receivable	--
Settlement deposit receivable	--
Prepaid and other assets	(62)
Accounts payable	(53)
Accrued expenses and other liabilities	(153)
	-----
Net cash used in operating activities	(4,726)
	-----
Cash flows from investing activities:	
Purchases of marketable securities	(4,108)
Proceeds from maturities and sales of marketable securities	2,704
Capital expenditures	--
	-----
Net cash used in investing activities	(1,404)
	-----
Cash flows from financing activities:	
Net proceeds from issuance of common stock	23,443
Distribution to minority interest stockholder	(54)
Principal payments of capital lease obligations	--
	-----
Net cash provided by (used in) financing activities	23,389
	-----
Net change in cash and cash equivalents	17,259
Cash and cash equivalents at beginning of period	24,923
	-----
Cash and cash equivalents at end of period	\$ 42,182
	=====

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

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

### 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, 2001.

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 Loss Per Common Share

-----

During the three month period ended December 31, 2001, 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 139,565 shares of Common Stock at exercise prices ranging from \$8.37 to \$20.13 with expiration dates ranging up to December 5, 2011; and (ii) warrants to purchase 550,000 shares of Common Stock with exercise prices ranging from \$7.88 to \$10.00 and with expiration dates ranging up to June 1, 2002. Additionally, during the three month period ended December 31, 2001, 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 9,394,165 shares of Common Stock at exercise prices ranging from \$1.47 to \$7.25 and expiration dates ranging up to November 26, 2011; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; (iii) warrants to purchase 130,000 shares of Common Stock at exercise prices ranging from \$5.00 to \$7.13 and expiration dates ranging up to July 17, 2006; and (iv) unvested Restricted Stock Awards of 225,000 shares of Common Stock granted pursuant to the Company's 1997 Equity Incentive Plan.

-6-

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;

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

(ii) 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.

### C. Comprehensive Loss

-----

Comprehensive loss for the three month periods ended December 31, 2001 and 2000, respectively, is as follows:

	Three Months Ended December 31, 2001	2000
	-----	-----
Net loss	\$(1,946,000)	\$(11,857,000)
Change in unrealized net gain or loss on investments	(124,000)	(594,000)
	-----	-----
Comprehensive loss	\$ (2,070,000)	\$ (12,451,000)
	=====	=====

### D. Equity

-----

In December 2001, the Company completed a private placement of 3,125,000 shares of its Common Stock which resulted in net proceeds to the Company of approximately \$23,400,000. In January 2002, the Company filed a registration statement on Form S-3 to register the resale of these shares.

### E. Recent Accounting Pronouncements

-----

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" ("SFAS No. 141") and SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2003. The impact of SFAS No. 141 and SFAS No. 142 on the Company's financial statements has not yet been determined.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). SFAS No. 144 supersedes FASB Statement No. 121, "Accounting

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of", and provides a single accounting model for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired. The provisions of SFAS No. 144 will be effective for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The Company does not expect SFAS No. 144 will have a material effect on its financial position or results of operations.

### 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 and other forward-looking statements made by the Company in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons, or our representatives are based on a number of assumptions and relate to, without limitation: the Company's ability to successfully develop, obtain regulatory approval for and commercialize any products; the Company's ability to enter into corporate collaborations or obtain sufficient additional capital to fund operations; and the Redux(TM)-related litigation. 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 such forward-looking statements may turn out to be wrong. 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, 2001. These factors include, but are not limited to: uncertainties relating to clinical trials, regulatory approval and commercialization of our 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 and insurance uncertainties; risks relating to the Redux-related litigation; dependence on third parties for manufacturing and marketing; competition; risks associated with contractual arrangements; limited patents and proprietary rights; and other risks. The forward-looking statements represent our judgement and expectations as of the date of this Form 10-Q. We assume 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, 2001. 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



## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

multiple compounds in late stage clinical development. The Company is currently developing or has certain rights to four core compounds which are the focus of the Company's development program: trospium for overactive bladder, pagoclone for panic and generalized anxiety disorders, PRO 2000 for the prevention of infection by the human immunodeficiency virus and other sexually transmitted pathogens, and dersalazine for inflammatory bowel disease.

-8-

### Products

Trospium is a muscarinic receptor antagonist in development as a treatment for overactive bladder. The Company is currently conducting a Phase III, double-blind, placebo-controlled study in approximately 500 patients, comparing both the number of micturitions and incontinence episodes among trospium-treated patients versus placebo-treated patients during a twelve week treatment period. The trial is expected to be completed in the fall of 2002. If the trial is successful, the Company plans to file a New Drug Application by the end of 2002.

Pagoclone is a novel GABA (gamma amino butyric acid) receptor agonist in development for the treatment of anxiety disorders. In December 2001, Pfizer Inc. ("Pfizer"), the Company's licensee for pagoclone, announced that in a Phase II clinical trial, patients treated with pagoclone experienced a statistically significant improvement in symptoms of generalized anxiety disorder ("GAD") compared to patients treated with placebo. In addition, pagoclone was well tolerated, with no difference from placebo in sedation and no evidence of withdrawal effects. As part of its comprehensive clinical development program for pagoclone, Pfizer is conducting a number of clinical trials, including a Phase III trial in panic disorder, multiple Phase II trials in GAD and multiple clinical pharmacology studies.

PRO 2000 is a topical microbicide in development for the prevention of the sexual transmission of HIV and other sexually-transmitted diseases. Multiple clinical trials in HIV prevention are expected to begin in 2002, including a Phase II trial sponsored by the European Commission and a Phase II/III trial to be conducted by the National Institutes of Health in approximately 10,000 women in Africa and India.

In September 2001, the Company acquired worldwide rights to dersalazine, an anti-inflammatory compound in clinical development to treat inflammatory bowel disease, which includes ulcerative colitis and Crohn's disease. The Company expects to complete a multiple-dose Phase I clinical study for dersalazine and initiate Phase II trials in ulcerative colitis in 2002.

### Results of Operations

Total revenues increased to \$3,541,000 in the three month period ended December 31, 2001 from \$360,000 in the three month period ended December 31, 2000. Royalty revenue, consisting of royalties received from Eli Lilly and Company ("Lilly") for sales of Sarafem, increased from \$360,000 in the first quarter of fiscal 2001 to \$3,199,000 in the first quarter of fiscal 2002. This substantial increase resulted from higher sales of Sarafem. The Company expects royalty payments from Sarafem to expire in March 2002 and the final royalty payment to be substantially decreased. Contract and license fee revenue of \$342,000 in the first quarter of fiscal 2002 consisted primarily of revenue from a research grant related to certain PRO 2000 development costs. Minimal additional future revenue will be recognized pursuant to this grant.

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

Cost of revenues of \$838,000 in the three month period ended December 31, 2001 consisted primarily of \$640,000 due to Massachusetts Institute of Technology ("MIT") for their portion of the Sarafem royalty revenue and the development costs related to the PRO 2000 research grant. Cost of revenues of \$72,000 in the three month period ended December 31, 2000 primarily relates to amounts due to MIT for their portion of the Sarafem royalty revenue recognized in the same period.

Research and development expense increased \$2,204,000, or 212%, to \$3,245,000 in the three month period ended December 31, 2001 compared to \$1,041,000 in the three month period ended December 31, 2000. This increase is primarily due to expenses incurred by the Company for its Phase III clinical trial for trospium which commenced in September 2001.

-9-

General and administrative expense decreased \$33,000, or 2%, to \$1,578,000 in the three month period ended December 31, 2001 from \$1,611,000 in the three month period ended December 31, 2000. This decrease was primarily due to the absence of legal fees relating to the Company's former suit against American Home Products Corporation ("AHP") principally offset by increased noncash charges for stock options previously granted to consultants of the Company which resulted from the significant increase in the price of the Company's Common Stock during the quarter ended December 31, 2001.

Investment income decreased \$279,000, or 55%, to \$228,000 in the three month period ended December 31, 2001 from \$507,000 in the three month period ended December 31, 2000. This decrease resulted from substantially reduced market interest rates from the first quarter of fiscal 2001 to the first quarter of fiscal 2002.

The charge for the cumulative effect of the change in accounting principle of \$10,000,000 in the three month period ended December 31, 2000 is related to the Company's adoption in fiscal 2001 of the Securities and Exchange Commissions Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements."

For the three month period ended December 31, 2001, the Company had a net loss of \$(1,946,000), or \$(0.04) per share, basic and diluted, compared to a net loss of \$(11,857,000), or \$(0.28) per share, basic and diluted, for the three month period ended December 31, 2000. The Company expects to report losses for its consolidated operations for fiscal 2002.

### Liquidity and Capital Resources

#### Cash, Cash Equivalents and Marketable Securities

At December 31, 2001, the Company had consolidated cash, cash equivalents and marketable securities of \$50,841,000 compared to \$32,171,000 at September 30, 2001. This increase of \$18,670,000 is primarily due to receipt of approximately \$23,400,000 of net proceeds from the Company's December 2001 private placement of 3,125,000 shares of Common Stock, offset primarily by approximately \$4,726,000 of cash used in operating activities.

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

The Company believes it has sufficient cash for currently planned expenditures for at least the next twelve months. Based on certain assumptions relating to operations and other factors, the Company may 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 to obtain such funds. 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. In particular, the Company expects to expend a substantial amount during the next twelve months to fund its on-going Phase III trial for tropsium. There can be no assurance that results of any on-going current

-10-

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 develop or commercialize any of its products.

### Analysis of Cash Flows

Cash used in operating activities during fiscal 2002 of \$4,726,000 consisted primarily of the net loss of \$(1,946,000) and an increase in accounts receivable primarily reflecting the \$3,199,000 of royalty revenue from Lilly which was collected in January 2002.

Cash used in investing activities in fiscal 2002 of \$1,404,000 consisted of net outflows from purchases of marketable securities.

Cash provided by financing activities in fiscal 2002 of \$23,389,000 consisted primarily of net proceeds from the Company's December 2001 private placement of 3,125,000 shares of its Common Stock.

### Insurance claim receivable

As of December 31, 2001, the Company had an outstanding insurance claim of approximately \$3,632,000, which the Company paid through December 31, 2001 to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to the Company by Reliance Insurance Company ("Reliance").

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with the Company's attorneys and other consultants regarding the amount and timing of potential collection of its claims against Reliance, the Company reduced the balance to an estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$1,258,000 reflected as a noncurrent insurance claim receivable at December 31, 2001. There can be no assurance that the Company will collect any of the \$3,632,000 claim. If the Company incurs additional product liability defense and other costs within the remaining limits of the \$5,000,000 Reliance product liability policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

### Other

Recent Accounting Pronouncements: In June 2001, the FASB issued SFAS No. 141, "Business Combinations" ("SFAS No. 141") and SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and

-11-

will thus be adopted by the Company as required, in fiscal year 2003. The impact of SFAS No. 141 and SFAS No. 142 on the Company's financial statements has not yet been determined.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). SFAS No. 144 supersedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of", and provides a single accounting model for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired. The provisions of SFAS No. 144 will be effective for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The Company does not expect SFAS No. 144 will have a material effect on its financial position or results of operations.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

-----

Interneuron owns financial instruments that are sensitive to market risks as part of its investment portfolio. The investment portfolio is used to preserve Interneuron's capital until it is required to fund operations, including Interneuron's research and development activities. None of these market-risk sensitive instruments are held for trading purposes. Interneuron does not own derivative financial instruments in its investment portfolio.

#### Interest Rate Risk

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

Interneuron invests its cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate and money market instruments. These investments are denominated in U.S. dollars. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Interneuron's investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and Interneuron has implemented guidelines limiting the duration of investments. Due to the conservative nature of these instruments, Interneuron does not believe that it has a material exposure to interest rate risk.

### 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

-12-

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 the Company paid any amounts in settlement of any of these claims.

The Company entered into the AHP Indemnity and Release Agreement on May 30, 2001 pursuant to which AHP agreed to indemnify the Company against certain classes of product liability cases filed against Interneuron related to Redux. The Company's indemnification covers existing plaintiffs who have already opted out of AHP's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, AHP has agreed to fund all future legal costs related to the Company's defense of Redux-related product

## Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

liability cases. The agreement also provides for AHP to fund additional insurance coverage to supplement the Company's existing product liability insurance. The Company believes this total insurance coverage is sufficient to address its potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which the Company is not otherwise indemnified or covered under the AHP Indemnity and Release Agreement will not have a material adverse effect on the Company's future business, results of operations or financial condition or that the potential of any such claims would not adversely affect the Company's ability to obtain sufficient financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the Company's defense costs were paid by, or subject to reimbursement to the Company from, the Company's product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Interneuron by AHP, the Company agreed to dismiss its suit against AHP filed in January 2000, its appeal from the order approving AHP's national class action settlement of diet drug claims, and its cross-claims against AHP related to Redux product liability legal actions.

**Insurance Litigation:** On August 7, 2001, Columbia Casualty Company, one of the Company's insurers for the period May 1997 through May 1998, filed an action in the United States District Court for the District of Columbia against the Company. The lawsuit is based upon a claim for breach of contract and declaratory judgment, seeking damages against the Company in excess of \$20,000,000, the amount that the plaintiff has paid to the Company under its insurance policy. The plaintiff alleges that under the policy it was subrogated to any claim for indemnification that Interneuron may have had against AHP related to Redux and that such claim was compromised without its consent when the Company entered into the AHP Indemnity and Release Agreement. The Company is vigorously defending this litigation.

**General:** Pursuant to agreements between the parties and related to the diet-drug litigation, under certain circumstances, the Company may be required to indemnify Les Laboratoires Servier, Boehringer Ingelheim Pharmaceuticals, Inc. and other parties.

-13-

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 event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against the Company and its officers and directors, the Company's business, financial condition and results of operations could be materially adversely affected. 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.

Edgar Filing: INTERNEURON PHARMACEUTICALS INC - Form 10-Q

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

(a) Exhibits

None

(b) Reports on Form 8-K

On December 20, 2001, the Company filed a report on Form 8-K announcing that Pfizer Inc. reported positive clinical trial results in generalized anxiety disorder with the Company's product pagoclone. The Company also reported on the progress of other clinical-stage products.

-14-

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, 2002

By: /s/ Glenn L. Cooper, M.D.  
-----

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

Date: February 14, 2002

By: /s/ Michael W. Rogers  
-----

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

Date: February 14, 2002

By: /s/ Dale Ritter  
-----

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

-15-