INTERNEURON PHARMACEUTICALS INC
Form 10-Q
August 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 June 30, 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 incorporation or organization)	(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 August 13 , 2001:
Common Stock $.001 par value	43,257,118 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)

	June 30, 2001	September 30, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$29,978	$24,871
Marketable securities	2,896	8,880
Insurance claim receivable	3,240	8,435
Settlement deposit receivable	--	1,757
Prepaids and other current assets	555	1,110
Total current assets	36,669	45,053
Investment in Incara	850	1,627
Marketable securities	2,002	--
Property and equipment, net	84	146
	$39,605	$46,826
LIABILITIES		
Current liabilities:		
Accounts payable	$ --	$ 122

Accrued expenses	6,153	15,604
Deferred revenue	3,000	3,000
Current portion of capital lease obligations	--	2
Total current liabilities	9,153	18,728
Minority interest	345	332
STOCKHOLDERS' EQUITY		
Preferred stock; $.001 par value, 5,000,000 shares authorized; Series B, 239,425 shares issued and outstanding at June 30, 2001 and September 30, 2000 (liquidation preference at June 30, 2001 $3,019)	3,000	3,000
Series C, 5,000 shares issued and outstanding at June 30, 2001 and September 30, 2000 (liquidation preference at June 30, 2001 $500)	500	500
Common stock; $.001 par value, 80,000,000 shares authorized; 43,257,118 and 42,780,492 shares issued and outstanding at June 30, 2001 and September 30, 2000, respectively	43	43
Additional paid-in capital	276,448	274,011
Accumulated deficit	(249,244)	(249,802)
Accumulated other comprehensive income	(640)	14
Total stockholders' equity	30,107	27,766
	$ 39,605	$ 46,826

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

INTERNEURON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the three and nine months ended June 30, 2001 and 2000
(Unaudited)
(Amounts in thousands except per share data)

	Three Months Ended June 30,		Nine Months Ended J
	2001	2000	2001
Revenues:			
Royalty income	$ 287	$ --	$ 932

Contract and license fees	--	--	--
Total revenues	287	--	932
Costs and expenses:			
Cost of revenues	70	24	200
Research and development	1,461	814	3,660
General and administrative	2,337	1,655	6,035
Product withdrawal	(7,480)	--	(8,098)
Total costs and expenses	(3,612)	2,493	1,797
Income (loss) from operations	3,899	(2,493)	(865)
Investment income, net	405	510	1,478
Gain (loss) on investment securities	--	--	(43)
Minority interest	(4)	--	(12)
Net income (loss)	$ 4,300	$(1,983)	$ 558
Net income (loss) per common share:			
Basic	$0.10	$ (0.05)	$0.01
Diluted	$0.09	$ (0.05)	$0.01
Weighted average common shares outstanding:			
Basic	42,970	42,730	42,843
Diluted	46,836	42,730	45,085

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

INTERNEURON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the nine months ended June 30, 2001 and 2000
(Unaudited)
(Amounts in thousands)

	Nine months ended June 30,	
	2001	2000
Cash flows from operating activities:		
Net income	$ 558	$ 15,158
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	80	168

Minority interest in net income of consolidated subsidiary	13	--
Gain on sales of property and equipment	--	(35)
Gain (loss) on investment securities	43	(1,550)
Noncash compensation	1,765	1,255
Change in assets and liabilities:		
Accounts receivable	--	517
Insurance claim receivable	5,195	(5,111)
Settlement deposit receivable	1,757	--
Prepaid and other assets	555	1,550
Accounts payable	(122)	(153)
Deferred revenue	--	3,000
Accrued expenses and other liabilities	(9,368)	(6,753)
Net cash provided by operating activities	476	8,046
Cash flows from investing activities:		
Capital expenditures	(18)	(8)
Proceeds from sales of property and equipment	--	40
Purchases of marketable securities	(5,983)	(12,378)
Proceeds from maturities and sales of marketable securities	9,971	7,371
Proceeds from sales of investment securities	--	1,756
Net cash provided by (used in) investing activities	3,970	(3,219)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	663	478
Principal payments of capital lease obligations	(2)	(61)
Net cash provided by financing activities	661	417
Net change in cash and cash equivalents	5,107	5,244
Cash and cash equivalents at beginning of period	24,871	19,354
Cash and cash equivalents at end of period	$29,978	$ 24,598

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

On May 30, 2001, the Company entered into an Indemnity and Release Agreement (the "AHP Agreement") with American Home Products Corporation ("AHP") which provides for AHP's indemnification of the Company with respect to certain classes of product liability claims filed against the Company related to the prescription drug Redux, which was withdrawn from the market in September 1997.

Pursuant to the AHP Agreement, AHP has agreed to indemnify and hold harmless the Company and its officers, directors and certain employees (collectively, "Interneuron Indemnified Parties") against all losses after the date of the AHP Agreement (including, damages, settlements and judgments) arising from Redux-related claims by (i) persons who have already opted out of AHP's National Class Action Settlement Agreement in Brown v. AHP, No. 99-20593 (E.D. Pa.) (the "Brown Settlement") and (ii) any Brown class member alleging Primary Pulmonary Hypertension (PPH) as a result of the use of Redux. AHP further agreed to assume the Company's defense in all litigation arising out of such indemnified claims.

In addition, AHP agreed to assume the defense of, and fund all future legal expenses in connection with, Redux-related product liability litigation brought by claimants other than those described above. AHP further agreed to provide additional insurance coverage to fund losses resulting from any settlements or judgments in current or future Redux-related product liability claims that are not covered by AHP's indemnification obligations under the AHP Agreement.

The Company believes that AHP's indemnification of certain claims, the insurance provided by AHP for other claims, and AHP's funding of legal expenses,

as described above, along with the Company's existing insurance, will be sufficient to address the Company's potential Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims that may arise in the future 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.

The AHP Agreement does not provide indemnification or defense by AHP of the Interneuron Indemnified Parties for losses and litigation expenses (i) incurred by Interneuron Indemnified Parties prior to the date of the Agreement, (ii) arising out of claims asserted against Interneuron Indemnified Parties for breaches or violations of any state or federal securities laws or (iii) any costs related to regulatory or government actions. Up to the date of the AHP

Agreement, the Company's defense costs had been and are being paid by its insurers. Further, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. Regarding securities litigation related to Redux, in 2000 several lawsuits naming certain directors and officers of the Company and claiming violation of federal securities laws were settled; the settlement amount was funded entirely by insurance proceeds. Also, the Company has not been involved in any regulatory or government actions relating to Redux.

Pursuant to the AHP Agreement, AHP and the Company agreed also to release each other from Redux-related claims. In addition, the Company agreed (i) to dismiss with prejudice its lawsuit, Interneuron v. AHP, No. 00-294 (Mass. Superior Court, Middlesex County), which the Company filed in January, 2000 (the "AHP Litigation"), (ii) to withdraw its appeal to the United States Third Circuit Court of Appeals from the order approving the Brown Settlement, and (iii) to dismiss its cross claims against AHP in all pending Redux-related product liability litigation.

As a result of the AHP Agreement, the Company believes that it is no longer probable that it will have to pay approximately $8,000,000 for estimated liabilities that had been established at the time Redux was withdrawn. Accordingly, the Company has reversed these accruals in the three month period ended June 30, 2001 and has reflected the reversal as a credit in product withdrawal in the Company's statements of operations. This credit is offset by a noncash charge of $561,000 for the fair value of stock options granted to attorneys involved in the AHP Litigation, resulting in a net credit of $7,480,000 in product withdrawal for the three month period ended June 30, 2001. Product withdrawal for the nine month period ended June 30, 2001 was a credit of $8,098,000 and additionally includes insurance reimbursements for other Redux-related expenses.

In fiscal 1999, the Company's three product liability insurers filed actions against Les Laboratoires Servier ("Servier") and the Company in the District Court for the Eastern District of Pennsylvania (the "District Court") pursuant to the federal interpleader statute. The aggregate limit 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 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 $8,419,000 for litigation expenses previously paid by the Company and for other Redux-related costs. Of this amount, $618,000 of other Redux-related costs are included as a credit in the Company's Statement of Operations for the nine month period ended June 30, 2001 under product withdrawal. Reflected in insurance claim receivable at June 30, 2001 of $3,240,000 is $2,552,000 which the Company paid through June 30, 2001 to the group of law firms defending the Company in the Redux-related product liability litigation and an additional $688,000 which the Company has

estimated and accrued for services rendered by such law firms through May 30, 2001. The Company currently intends to finalize payments for such fees and to file claims for reimbursement from the insurance companies. The insurance company from whom the Company is currently seeking reimbursement for its outstanding claims has notified the Company that it is in rehabilitation.

Rehabilitation, in Pennsylvania, is a court-ordered action authorized under the state's insurance laws that places the state's Insurance Commissioner as the "Rehabilitator" in control over an insurance company whereby the Rehabilitator conducts an analysis of the insurance company's financial position and determines what steps are feasible and necessary to correct the insurance company's problems while giving priority to protecting the policyholders. The insurance company has indicated to the Company that the Company's claims on its policy will be paid although there can be no assurance the Company will receive such reimbursements. The Company expects to be reimbursed for Redux-related product liability insurance claims until the aggregate limits of its other commercial excess insurance policies are paid.

In October 2000, 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 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 Agreement. The Company is evaluating the lawsuit and plans to vigorously defend this litigation.

C. 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 June 30,		Nine Months Ended June	
	2001	2000	2001	
Numerator for basic and diluted income (loss) per share:				
Net income (loss)	$ 4,300,000	$(1,983,000)	$ 558,000	$1
Denominator for basic income (loss) per share:				
Weighted average shares outstanding	42,970,000	42,730,000	42,843,000	42
Denominator for diluted income (loss) per share:				
Weighted average shares outstanding	42,970,000	42,730,000	42,843,000	42,
Dilutive effect of:				
Shares issuable in connection with stock option plans	2,904,000	--	1,206,000	
Shares issued or issuable in connection with restricted stock awards	340,000	--	414,000	7
Shares issuable in connection with convertible preferred stock	622,000	--	622,000	6

Weighted average shares outstanding - diluted	46,836,000	42,730,000	45,085,000	43,8
Net income (loss) per common share - Basic	$ 0.10	$ (0.05)	$ 0.01	$
Diluted	$ 0.09	$ (0.05)	$ 0.01	$

During the three month period ended June 30, 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 2,953,041 shares of Common Stock at prices ranging from $6.00 to $20.13 with expiration dates ranging up to April 5, 2010; and (ii) warrants to purchase 660,000 shares of Common Stock with exercise prices ranging from $6.19 to $12.77 and with expiration dates ranging up to July 17, 2006.

During the three month period ended June 30, 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 9,535,150 shares of Common Stock at prices ranging from $2.38 to $20.13 with expiration dates ranging up to April 5, 2010; and (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. Additionally, during the three month period ended June 30, 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 187,801 shares of Common Stock at prices ranging from $1.53 to $1.88 with expiration dates ranging up to June 6, 2007; (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.

During the nine month period ended June 30, 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 5,972,042 shares of Common Stock at prices ranging from $3.56 to $20.13 with expiration dates ranging up to March 8, 2011; and (ii) warrants to purchase 660,000 shares of Common Stock with exercise prices ranging from $6.19 to $12.77 and with expiration dates ranging up to July 17, 2006.

During the nine month period ended June 30, 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 6,326,979 shares of Common Stock at prices ranging from $3.56 to $20.13 with expiration dates ranging up to March 9, 2010; (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 up to December 31, 1999.

D. Comprehensive Income (Loss)

Comprehensive income (loss) for the three and nine month periods ended June

30, 2001 and 2000, respectively, is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2001	2000	2001	2000
Net income (loss)	$4,300,000	$(1,983,000)	$ 558,000	$15,158,000
Change in unrealized net gain or loss on investments	7,000	(1,514,000)	(654,000)	(361,000)
Comprehensive income (loss)	$4,307,000	$(3,497,000)	$ (96,000)	$14,797,000

9

E. Other 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 III development for the treatment and prevention of liver diseases, including alcohol and Hepatitis C-induced cirrhosis. In exchange for potential future milestone payments and royalties on potential 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 in the licensed territory.

F. Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("the "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 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 delayed the implementation date of SAB 101. The Company will adopt SAB 101 in the fourth quarter of fiscal 2001. The Company is currently assessing the impact of SAB 101, the adoption of which could have a

significant noncash effect on the Company's results of operations for fiscal 2001. To the extent the adoption of SAB 101 results in the deferral of revenue recognized prior to fiscal 2001 in connection with the Company's collaboration with Takeda Chemical Industries, Ltd. ("Takeda"), such deferral would be reflected as a cumulative effect of a change in accounting principle in the Company's statement of operations.

In June 1998, the FASB issued 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 No. 133 in the fiscal quarter ended December 31, 2000 and the adoption did not have an impact on the Company's financial statements.

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: uncertainties relating to clinical trials, regulatory approvals and commercialization of the Company's products; need for additional funds and corporate partners; history of operating losses and expectation of future losses; risks relating to the Redux-related litigation; product liability; dependence on third parties for manufacturing and marketing; the early stage of products under development; government regulation; risks associated with contractual agreements; dependence upon key personnel; uncertainty regarding pharmaceutical pricing and reimbursement; limited patent protection and proprietary rights and competition 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 liver diseases, citicoline for ischemic stroke, and PRO 2000 for the prevention of infection by the human immunodeficiency virus ("HIV") and for the prevention of sexually transmitted diseases. 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.

Redux

On May 30, 2001, the Company entered into an Indemnity and Release Agreement (the "AHP Agreement") with American Home Products Corporation ("AHP") which provides for AHP's indemnification of the Company with respect to certain classes of product liability claims filed against the Company related to the prescription drug Redux, which was withdrawn from the market in September 1997.

Pursuant to the AHP Agreement, AHP has agreed to indemnify and hold harmless the Company and its officers, directors and certain employees (collectively, "Interneuron Indemnified Parties") against all losses after the date of the AHP Agreement (including damages, settlements and judgments) arising from Redux-related claims by (i) persons who have already opted out of AHP's National Class Action Settlement Agreement in Brown v. AHP, No. 99-20593 (E.D. Pa.) (the "Brown Settlement") and (ii) any Brown class member alleging Primary Pulmonary Hypertension (PPH) as a result of the use of Redux. AHP further agreed to assume the Company's defense in all litigation arising out of such indemnified claims.

In addition, AHP agreed to assume the defense of, and fund all future legal expenses in connection with, Redux-related product liability litigation brought by claimants other than those described above. AHP further agreed to provide additional insurance coverage to fund losses resulting from any settlements or judgments in current or future Redux-related product liability claims that are not covered by AHP's indemnification obligations under the AHP Agreement.

The Company believes that AHP's indemnification of certain claims, the insurance provided by AHP for other claims, and AHP's funding of legal expenses, as described above, along with the Company's existing insurance, will be sufficient to address the Company's potential Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims that may arise in the future 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.

The AHP Agreement does not provide indemnification or defense by AHP of the Interneuron Indemnified Parties for losses and litigation expenses (i) incurred by Interneuron Indemnified Parties prior to the date of the Agreement, (ii) arising out of claims asserted against Interneuron Indemnified Parties for breaches or violations of any state or federal securities laws or (iii) any costs related to regulatory or government actions. Up to the date of the AHP Agreement, the Company's defense costs had been and are being paid by its insurers. Further, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. Regarding securities litigation related to Redux, in 2000 several lawsuits naming certain directors and officers of the Company and claiming violation of federal securities laws were settled; the settlement amount was funded entirely by insurance proceeds. Also, the Company has not been involved in any regulatory or government actions relating to Redux.

Pursuant to the AHP Agreement, AHP and the Company agreed also to release each other from Redux-related claims. In addition, the Company agreed (i) to dismiss with prejudice its lawsuit, Interneuron v. AHP, No. 00-294 (Mass. Superior Court, Middlesex County), which the Company filed in January, 2000 (the "AHP Litigation"), (ii) to withdraw its appeal to the United States Third Circuit Court of Appeals from the order approving the Brown Settlement, and (iii) to dismiss its cross claims against AHP in all pending Redux-related product liability litigation.

As a result of the AHP Agreement, the Company believes that it is no longer probable that it will have to pay approximately $8,000,000 for estimated liabilities that had been established at the time Redux was withdrawn. Accordingly, the Company has reversed these accruals in the three month period ended June 30, 2001 and has reflected the reversal as a credit in product withdrawal in the Company's statements of operations. This credit is offset by a noncash charge of $561,000 for the fair value of stock options granted to attorneys involved in the AHP Litigation, resulting in a net credit of $7,480,000 in product withdrawal for the three month period ended June 30, 2001. Product withdrawal for the nine month period ended June 30, 2001 was a credit of $8,098,000 and additionally includes insurance reimbursements for other Redux-related expenses.

In fiscal 1999, the Company's three product liability insurers filed actions against Les Laboratoires Servier ("Servier") and the Company in the District Court for the Eastern District of Pennsylvania (the "District Court") pursuant to the federal interpleader statute. The aggregate limit 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 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 $8,419,000 for litigation expenses previously paid by the Company and for other Redux-related costs. Of this amount, $618,000 of other Redux-related costs are included as a credit in the Company's Statement of Operations for the nine month period ended June 30, 2001 under product withdrawal. Reflected in insurance claim receivable at June 30, 2001 of $3,240,000 is $2,552,000 which the Company paid through June 30, 2001 to the group of law firms defending the Company in the Redux-related

product liability litigation and an additional $688,000 which the Company has estimated and accrued for services rendered by such law firms through May 30, 2001. The Company currently intends to finalize payments for such fees and to file claims for reimbursement from the insurance companies. The insurance company from whom the Company is currently seeking reimbursement for its outstanding claims has notified the Company that it is in rehabilitation. Rehabilitation, in Pennsylvania, is a court-ordered action authorized under the state's insurance laws that places the state's Insurance Commissioner as the "Rehabilitator" in control over an insurance company whereby the Rehabilitator conducts an analysis of the insurance company's financial position and determines what steps are feasible and necessary to correct the insurance company's problems while giving priority to protecting the policyholders. The insurance company has indicated to the Company that the Company's claims on its policy will be paid, although there can be no assurance the Company will receive such reimbursements. The Company expects to be reimbursed for Redux-related product liability insurance claims until the aggregate limits of its other commercial excess insurance policies are paid.

In October 2000, 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 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 Agreement. The Company is evaluating the lawsuit and plans to vigorously defend this litigation.

See "Liquidity and Capital Resources - Analysis of Cash Flows" and "PART II. Item 1. Legal Proceedings."

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 potential payments to be received by the Company from Pfizer. Pfizer is currently testing pagoclone in a Phase III trial for panic disorder and a Phase II trial for generalized anxiety 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 U.S. Food and Drug Administration ("FDA"), the Company elected to conduct a standardized electrocardiographic 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 Phase III 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 has since completed the safety study. The Company expects to begin a 500-patient Phase III trial in the fall of 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 III development for the treatment and prevention of liver diseases, including alcohol and Hepatitis C-induced cirrhosis.

IP 501 is currently being studied in an 800-patient Phase III clinical trial sponsored by the Veterans Administration. Data analysis from the trial 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 III trial designed to evaluate the safety and effectiveness of IP 501 in treating patients with Hepatitis C-associated cirrhosis.

In April 2001, Takeda Chemical Industries Ltd. ("Takeda") exercised a previously granted option to negotiate a license to one of the Company's compounds (see "Citicoline"). Takeda has designated IP 501 as such compound. Takeda will have a 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. Upon the expiration of such six month period on October 1, 2001, in the event the Company has not entered into an agreement with Takeda, Takeda will have no further rights to IP 501.

PRO 2000

In June 2000, the Company licensed exclusive, worldwide rights 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 I/Phase II 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 PRO 2000 was judged by investigators to be safe and well tolerated. Additional government-funded clinical testing is planned, including a Phase II/Phase III clinical trial to evaluate long-term safety and protective efficacy against HIV.

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 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. The maximum aggregate royalty payments to Interneuron in any calendar year range 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 expires in August 2001. As a result, the Company expects royalty payments under this agreement to cease in early 2002.

Citicoline

In December 1999, the Company entered into an agreement with 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 exercised its option under the Takeda Agreement to negotiate a license of another one of the Company's compounds and has selected IP 501 as such compound.

Results of Operations

Fiscal 2001 revenues consisted of $287,000 and $932,000 of royalty revenue received from Lilly on sales of Sarafem in the three and nine month periods ended June 30, 2001, respectively. Fiscal 2000 revenue in the nine month period ended June 30, 2000 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. The Company reported no revenue in the three month period ended June 30, 2000.

Cost of revenues of $70,000 and $200,000 in the three and nine month periods ended June 30, 2001, respectively, consists primarily of amounts due or paid to Massachusetts Institute of Technology for its portion of the Sarafem royalty revenue. Cost of revenues of $2,075,000 in the nine month period ended June 30, 2000 reflect payments to Aventis for its portion of the initial license payment received by the Company from Pfizer.

Research and development expense increased $647,000, or 79%, to $1,461,000 in the three month period ended June 30, 2001 from $814,000 in the three month period ended June 30, 2000, and increased $570,000, or 18%, to $3,660,000 in the nine month period ended June 30, 2001 from $3,090,000 in the nine month period ended June 30, 2000. The increase in the three month period primarily reflects increased clinical-related costs for the development of trospium and PRO 2000 and a relative increase due to the reversal of accruals in the fiscal 2000 three month period related to the end of the citicoline trial, partially offset by a decrease due to the initial PRO 2000 license payment recorded in the fiscal 2000 three month period. The increase in the nine month period is primarily due to $1,800,000 of credits recorded in the nine month period ended June 30, 2000 reflecting the reversal of costs accrued relative to the Phase 3 citicoline clinical trial, which were determined to be unnecessary, and reversal of expense accrued for pagoclone development which was determined to be unnecessary subsequent to the Pfizer Agreement. In the fiscal 2001 nine month period, the Company also incurred increased clinical-related costs for the development of PRO 2000, trospium, and IP 501. These increases were offset by reductions in expense due to the completion of the Phase III citicoline clinical trial in fiscal 2000, the initial PRO 2000 license payment recorded in fiscal 2000, and reduced payroll and employee-related expenses resulting from

reductions in staffing in fiscal 2000. Research and development expenses are expected to increase in future periods due to the initiation of new trospium and PRO 2000 clinical studies.

General and administrative expense increased $682,000, or 41%, to $2,337,000 in the three month period ended June 30, 2001 from $1,655,000 in the three month period ended June 30, 2000, and decreased $246,000, or 4%, to $6,035,000 in the nine month period ended June 30, 2001 from $6,281,000 in the nine month period ended June 30, 2000. The increase in the three month period is due primarily to the significant increase in the price of the Company's Common Stock in the three month period which resulted in recording increased noncash charges for stock options which were granted to consultants of the Company in lieu of cash compensation. Expense reductions in the nine month period includes reduced expense related to restricted stock awards granted pursuant to the Company's 1997 Equity Incentive Plan, reduced payroll and employee-related expenses resulting from reductions in staffing and reduced insurance, facilities and consultant expense. These nine month period reductions were substantially offset by increased noncash charges from stock options which were granted to consultants to the Company in lieu of cash compensation and increased costs related to the Company's lawsuit against AHP, which lawsuit has been dismissed pursuant to the AHP Agreement.

As a result of the AHP Agreement, the Company believes that it is no longer probable that it will have to pay approximately $8,000,000 for estimated liabilities that had been established at the time Redux was withdrawn. Accordingly, the Company has reversed these accruals in the three month period ended June 30, 2001 and has reflected the reversal as a credit in product withdrawal in the Company's statements of operations. This credit is offset by a noncash charge of $561,000 for the fair value of stock options granted to attorneys involved in the AHP Litigation resulting in a net credit of $7,480,000 in product withdrawal for the three month period ended June 30, 2001. Product withdrawal for the nine month period ended June 30, 2001 was a credit of $8,098,000 and additionally includes insurance reimbursements for other Redux-related expenses.

Investment income, net decreased $105,000, or 21%, to $405,000 in the three month period ended June 30, 2001 from $510,000 in the three month period ended June 30, 2000, and increased $175,000, or 13%, to $1,478,000 in the nine month period ended June 30, 2001 from $1,303,000 in the nine month period ended June 30, 2000. The decrease in the three month period is primarily due to lower interest rates on slightly higher average invested balances. While yields were lower in the nine month period ended June 30, 2001 than the nine month period ended June 30, 2000, average invested balances were significantly higher resulting in an increase in investment income, net in fiscal 2001.

Gain on investment securities of $1,550,000 in the nine month period ended June 30, 2000 resulted from the Company's sale of 288,000 shares of Incara Pharmaceuticals Corporation ("Incara") stock. The loss on investment securities of $43,000 in the nine month period ended June 30, 2001 additionally related to Incara stock.

For the three month period ended June 30, 2001, the Company had net income of $4,300,000, or $0.09 per share, diluted, compared to net loss of $(1,983,000), or $(0.05) per share, diluted, for the three month period ended June 30, 2000. For the nine month period ended June 30, 2001, the Company had net income of $558,000, or $0.01 per share, diluted, compared to net income of $15,158,000, or $0.35 per share, diluted, for the nine month period ended June 30, 2000. The change to net income from net loss in the three month period ended June 30, 2001 is primarily the result of the items discussed above, the most notable being the product withdrawal credit. The decrease in net income in the nine month period ended June 30, 2001 is primarily due to the absence of

contract and license fee revenue from Takeda and Pfizer reflected in the fiscal 2000 nine month period being partially offset by the product withdrawal credit recorded in the fiscal 2001 nine month period. The Company currently expects to incur loses for its consolidated operations in fiscal 2001.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At June 30, 2001, the Company had consolidated cash, cash equivalents and marketable securities of $34,876,000 compared to $33,751,000 at September 30, 2000. This increase of $1,125,000 is primarily due to the receipt of $8,419,000 in January 2001 of insurance claims, net of approximately $4,100,000 of payments, relating to the group of legal firms representing the Company in its Redux-related product liability litigation, $1,757,000 returned to the Company from the District Court and reflected at September 31, 2000 as settlement deposit receivable, and $663,000 of proceeds from the issuance of Common Stock, substantially offset by funding the Company's operations for the nine month period ended June 30, 2001. See "Analysis of Cash Flows" and "Part II, Item 1. Legal Proceedings."

While the Company believes it has sufficient cash for currently planned expenditures for the next twelve months, based on certain assumptions relating to operations and other factors, 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. 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, due to uncertainties associated with the Redux-related litigation, market conditions and other factors generally affecting the Company's ability to raise capital.

Product Development

The Company expects to continue to expend substantial additional amounts for the development of its products. There can be no assurance that results of any ongoing 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

Reflected in insurance claim receivable at June 30, 2001 of $3,240,000 is $2,552,000 which the Company paid to the group of law firms defending the Company in the Redux-related product liability litigation and an additional estimated $688,000 which the Company owes to such law firms for services rendered (see "Part II, Item 1. Legal Proceedings"). In January 2001, the Company received an $8,419,000 payment of insurance claims. Following the AHP Agreement as of May 30, 2001, AHP has assumed defense and related costs of the Company's product liability litigation. The Company does not expect to make significant additional payments to the group of law firms defending the Company

for Redux-related product liability litigation.

Accrued expenses and other liabilities decreased $9,368,000 in the nine month period June 30, 2001 primarily as a result of the reversal of Redux withdrawal-related liabilities and a reduction in the amount accrued for services provided by the law firms providing Redux-related product liability litigation services.

Other

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("the "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 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 delayed the implementation date of SAB 101. The Company will adopt SAB 101 in the fourth quarter of fiscal 2001. The Company is currently assessing the impact of SAB 101, the adoption of which could have a significant noncash effect on the Company's results of operations for fiscal 2001. To the extent the adoption of SAB 101 results in the deferral of revenue recognized prior to fiscal 2001 in connection with the Company's collaboration with Takeda, such deferral would be reflected as a cumulative effect of a change in accounting principle in the Company's statement of operations.

In June 1998, the FASB issued 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 No. 133 in the fiscal quarter ended December 31, 2000 and the adoption did not have an impact on the Company's 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 ("District Court") for coordinated or consolidated pretrial proceedings. To date, there have been no settlements or judgments against the Company. Following the dismissal and the anticipated dismissal of Interneuron as a defendant in certain cases, the Company estimates that there will be fewer than 1,700 remaining cases.

Objection to AHP's Settlement of Diet-Drug Litigation: On November 23, 1999, the District Court preliminarily approved a nationwide settlement of AHP's diet-drug litigation. The Company is not a released party under this settlement. To preserve any contribution or indemnification rights it may have against AHP, the Company objected to the Brown Settlement and filed an appeal from the District Court's August 28, 2000 order finally approving the settlement to the Third Circuit Court of Appeals. Pursuant to the May 30, 2001 AHP Agreement, the Company withdrew its objection to the Brown Settlement (See "AHP Agreement" below).

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 limit 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. 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 the filing of a complaint against AHP in the Superior Court of the Commonwealth of Massachusetts. The complaint sought 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. Pursuant to the AHP Agreement described below, the Company dismissed its complaint against AHP with prejudice.

AHP Agreement: On May 30, 2001, the Company and AHP entered into the AHP Agreement. Under the terms and conditions of the AHP Agreement, AHP will (i) defend and indemnify the Company against all claims and any judgments or settlements in diet-drug litigation brought by persons who have exercised their

right to opt-out of the Brown Settlement ("initial opt-outs") and by persons pursuing claims alleging Primary Pulmonary Hypertension (PPH), (ii) defend the Company from any and all claims existing now or brought in the future by diet-drug litigants other than initial opt-outs from the Brown Settlement, and (iii) fund additional insurance coverage to supplement the Company's existing product liability insurance. In exchange for these considerations, the Company agreed to (i) to dismiss with prejudice its lawsuit, Interneuron v. AHP, No. 00-294 (Mass. Superior Court, Middlesex County), which the Company filed in January, 2000, (ii) to withdraw its appeal to the United States Third Circuit Court of Appeals from the order approving the Brown Settlement, and (iii) to dismiss its cross claims against AHP in all pending Redux-related product liability litigation.

Complaint by Product Liability Insurer: 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 Agreement. The Company is evaluating the lawsuit and plans to vigorously defend this litigation.

General: Pursuant to agreements between the parties, under certain circumstances, the Company may be required to indemnify Servier and Boehringer Ingelheim Pharmaceuticals, Inc. against certain claims, damages or liabilities incurred in connection with Redux.

Although the Company maintains certain product liability and director and officer liability insurance and intends to defend these and any similar actions vigorously, the Company has been required and may continue to be required to devote significant management time and resources to such 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, 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.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

1.120 Indemnity and Release Agreement between American Home Products Corporation and Interneuron Pharmaceuticals, Inc. dated as of May 30, 2001 (1)

(1) Confidential treatment requested.

(b) Reports on Form 8-K

On June 14, 2001, the Company filed a report on Form 8-K reporting the AHP Agreement.

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: August 14, 2001

By: /s/ Glenn L. Cooper

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

Date: August 14, 2001

By: /s/ Michael W. Rogers

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

Date: August 14, 2001

By: /s/ Dale Ritter

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