INDEVUS PHARMACEUTICALS INC
Form 10-Q
May 15, 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 March 31, 2002, 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

INDEVUS 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) | 02421-7966 (Zip Code) |

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

Former name: Interneuron Pharmaceuticals, Inc.

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 May 10, 2002: |
|---|---|
| Common Stock $.001 par value | 46,608,014 shares |

INDEVUS PHARMACEUTICALS, INC.

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Item 1. Financial Statements

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

| | March 31, 2002 | Sept |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 26,385 | $ |
| Marketable securities | 13,375 | |
| Accounts receivable | 175 | |
| Prepaids and other current assets | 605 | |

| | | |
|---|---|---|
| Total current assets | 40,540 | |
| Marketable securities | 10,258 | |
| Equity securities | 376 | |
| Property and equipment, net | 25 | |
| Insurance claim receivable | 1,258 | |
| Total assets | $ 52,457 | $ |
| LIABILITIES | | |
| Current liabilities: | | |
| Accounts payable | $ 122 | $ |
| Accrued expenses | 4,538 | |
| Total current liabilities | 4,660 | |
| Minority interest | 98 | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock; $.001 par value, 5,000,000 shares authorized; | | |
| Series B, 239,425 shares issued and outstanding (Liquidation preference at March 31, 2002 $3,041) | 3,000 | |
| Series C, 5,000 shares issued and outstanding (liquidation preference at March 31, 2002 $504) | 500 | |
| Common stock; $.001 par value, 80,000,000 shares authorized; | | |
| 46,608,014 and 43,283,016 shares issued and outstanding at March 31, 2002 and September 30, 2001, respectively | 47 | |
| Additional paid-in capital | 302,584 | |
| Accumulated deficit | (258,047) | ( |
| Accumulated other comprehensive income (loss) | (385) | |
| Total stockholders' equity | 47,699 | |
| Total liabilities and stockholders' equity | $ 52,457 | $ |

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



INDEVUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the three and six months ended March 31, 2002 and 2001
(Unaudited)
(Amounts in thousands except per share data)

Three months ended March 3

| | 2002 | 2001 |
|---|---|---|
| Revenues: | | |
| Royalty revenue | $ 14 | $ 285 |
| Contract and license fee revenue | 72 | -- |
| Total revenues | 86 | 285 |
| Costs and expenses: | | |
| Cost of revenues | 85 | 58 |
| Research and development | 2,501 | 1,157 |
| General and administrative | 2,605 | 2,087 |
| Product withdrawal | -- | (618 |
| Total costs and expenses | 5,191 | 2,684 |
| Loss from operations | (5,105) | (2,399 |
| Investment income, net | 298 | 566 |
| Loss on equity securities | -- | (43 |
| Minority interest | (1) | (9 |
| Loss before cumulative effect of change in accounting principle | (4,808) | (1,885 |
| Cumulative effect of change in accounting principle | -- | -- |
| Net loss | $ (4,808) | $ (1,885 |
| Loss per common share-basic and diluted: | | |
| Loss before cumulative effect of change in accounting principle | $ (0.10) | $ (0.04 |
| Cumulative effect of change in accounting principle | -- | -- |
| Net loss | $ (0.10) | $ (0.04 |
| Weighted average common shares outstanding: | | |
| Basic and diluted | 46,508 | 42,781 |

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



INDEVUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the six months ended March 31, 2002 and 2001
(Unaudited)
(Amounts in thousands)

| | Six months ended |
|---|---|

| | 2002 | |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $ (6,754) | $ |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | |
| Cumulative effect of change in accounting principle | -- | |
| Depreciation and amortization | 46 | |
| Minority interest in net income of consolidated subsidiary | 55 | |
| Loss on equity securities | -- | |
| Noncash compensation | 2,139 | |
| Changes in assets and liabilities: | | |
| Accounts receivables | 156 | |
| Insurance claim receivable | -- | |
| Settlement deposit receivable | -- | |
| Prepaid and other assets | (208) | |
| Accounts payable | 69 | |
| Accrued expenses and other liabilities | (1,586) | |
| Net cash (used in) provided by operating activities | (6,083) | |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (21,132) | |
| Proceeds from maturities and sales of marketable securities | 4,668 | |
| Capital expenditures | (4) | |
| Net cash used in investing activities | (16,468) | |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of common stock | 24,067 | |
| Distribution to minority interest stockholder | (54) | |
| Principal payments of capital lease obligations | -- | |
| Net cash provided by financing activities | 24,013 | |
| Net change in cash and cash equivalents | 1,462 | |
| Cash and cash equivalents at beginning of period | 24,923 | |
| Cash and cash equivalents at end of period | $ 26,385 | $ |

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



INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

The consolidated financial statements included herein have been prepared by Indevus Pharmaceuticals, Inc. ("Indevus" 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.

Indevus 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 March 31, 2002, 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 55,000 shares of Common Stock at prices ranging from $9.88 to $20.13 with expiration dates ranging up to December 16, 2006; and (ii) a warrant to purchase 500,000 shares of Common Stock with an exercise price of $10.00 and with an expiration date of July 12, 2002. Additionally, during the three month period ended March 31, 2002, 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 9,659,640 shares of Common Stock at prices ranging from $1.47 to $8.75 with expiration dates ranging up to December 5, 2011; (ii) warrants to purchase 155,000 shares of Common Stock with exercise prices ranging from $5.00 to $7.88 and with expiration dates ranging up to July 17, 2006; (iii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; and (iv) unvested Restricted Stock Awards of 225,000 shares of Common Stock granted pursuant to the Company's 1997 Equity Incentive Plan.

During the three month period ended March 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 5,907,790 shares of Common Stock at prices ranging from $3.13 to $20.13 with expiration dates ranging up to March 8, 2011; 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 March 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 3,781,750 shares of Common Stock at prices ranging from $1.47 to $2.38 with expiration dates ranging up to August 14, 2010; (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 six month period ended March 31, 2002, 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 75,000 shares of Common Stock at prices ranging from $8.75 to $20.13 with expiration dates ranging up to December 16, 2006; and (ii) a warrant to purchase 500,000 shares of Common Stock with an exercise price of $10.00 and with an expiration date of July 12, 2002. Additionally, during the six month period ended March 31, 2002, 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 9,587,751 shares of Common Stock at prices ranging from $1.47 to $8.37 with expiration dates ranging up to December 12, 2011; (ii) warrants to purchase 155,000 shares of Common Stock with exercise prices ranging from $5.00 to $7.88 and with expiration dates ranging up to July 17, 2006; (iii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; and (iv) unvested Restricted Stock Awards of 225,000 shares of Common Stock granted pursuant to the Company's 1997 Equity Incentive Plan.

During the six month period ended March 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 9,145,790 shares of Common Stock at prices ranging from $2.38 to $20.13 with expiration dates ranging up to March 8, 2011; 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 six month period ended March 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 543,750 shares of Common Stock at prices ranging from $1.47 to $2.06 with expiration dates ranging up to August 14, 2010; (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.

Certain of the above securities contain anti-dilution provisions which may result in a change in the exercise price or number of shares issuable upon exercise of such securities.

C. Comprehensive Loss

Comprehensive loss for the three and six month periods ended March 31, 2002 and 2001, respectively, is as follows:

| | Three Months Ended March 31, | | Six Months Ended Marc | |
|---|---|---|---|---|
| | 2002 | 2001 | 2002 | 200 |
| Net loss | $(4,808,000) | $(1,885,000) | $(6,754,000) | $(13,74 |
| Change in unrealized net gain or loss on investments | (272,000) | (67,000) | (396,000) | (66 |
| Comprehensive loss | $(5,080,000) | $(1,952,000) | $(7,150,000) | $(14,40 |

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 $23,300,000. A Form S-3 registration statement registering the resale of these shares became effective in March 2002.

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 Company does not expect the adoption of SFAS No. 141 and SFAS No. 142 to have a material effect on the Company's financial condition or results of operations.



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 2. Management's Discussion and Analysis of Financial Condition 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 patent 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, "Indevus" or the "Company" refer to Indevus Pharmaceuticals, Inc.

General

Description of the Company

Indevus 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 six compounds: pagoclone for panic and generalized anxiety disorders, trospium for the treatment of overactive bladder, IP 501 for the treatment of cirrhosis of the liver, citicoline for the treatment of ischemic stroke, PRO 2000 for the prevention of infection by the human immunodeficiency virus and other sexually transmitted pathogens, and dersalazine for the treatment of inflammatory bowel disease.

Major 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 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 currently plans to file a U.S. New Drug Application ("NDA") 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 multiple clinical pharmacology studies and is nearing the completion of a series of Phase II trials in GAD and a Phase III

trial in panic disorder. Under the Company's agreement with Pfizer (the "Pfizer Agreement"), by June 23, 2002, Pfizer will be obligated to pay the Company a $10,000,000 milestone payment in order to retain its rights under the Pfizer Agreement.

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 with PRO 2000 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 February 2002, an international research collaboration received a grant of approximately $22.7 million from the U.K.'s Department for International Development to test the safety and efficacy of vaginal microbicides, including PRO 2000. This grant will support a broad, five-year program that will include a multi-national, Phase III clinical trial of candidate microbicides.

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 commenced a multiple-dose Phase I clinical study with dersalazine in March 2002 and expects the trial to be completed in the third quarter of 2002. Pending a positive outcome of this trial, the Company expects to begin testing dersalazine in patients with ulcerative colitis prior to the end of 2002.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are constantly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

In December 2001, the SEC requested that all registrants discuss their "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. A critical accounting policy is a policy that is both important to the portrayal of the Company's financial conditions and results, and requires management's most difficult, subjective or complex judgements and estimates. While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements included in our Form 10-K for the fiscal year ended September 30, 2001, we consider our revenue recognition policy critical and therefore we state it below.

Revenue Recognition: Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-

refundable license fees are recognized as contract and license fee revenue when the Company has a contractual right to receive such payment, provided a contractual arrangement exists, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement.

Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company's licensed technologies and is recognized when the amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

Cash received in advance of revenue recognition is recorded as deferred revenue.

Results of Operations

Total revenues decreased to $86,000 in the three month period ended March 31, 2002 from $285,000 in the three month period ended March 31, 2001 and increased to $3,627,000 in the six month period ended March 31, 2002 from $645,000 in the six month period ended March 31, 2001. Royalty revenue was derived from sales of Sarafem by Eli Lilly and Company ("Lilly") and contract and license fee revenue resulted from a research grant related to certain PRO 2000 development costs. The substantial increase in Sarafem royalties in the six month period ended March 31, 2002 resulted from approximately $3,199,000 of royalties recognized in the first quarter of fiscal 2002 from higher sales of Sarafem. Royalty revenue decreased to $14,000 in the second quarter of fiscal 2002 as a result of the achievement by Lilly of the maximum amount of royalties in the contractual royalty year. Lilly has notified the Company that the Company should not expect to receive future Sarafem royalties. The Company and Lilly differ in the interpretation of certain provisions of the Sarafem license agreement, including the contractual duration of the Sarafem royalties, and are currently discussing a resolution of these differences. Additionally, the Company has recognized the full amount of revenue available from the PRO 2000 research grant.

Cost of revenues for each period includes amounts due to Massachusetts Institute of Technology for their portion of the Sarafem royalty revenue. Additionally, costs of revenues for the three and six month periods ended March 31, 2002 include the development costs related to the PRO 2000 research grant.

Research and development expense increased $1,344,000, or 116%, to $2,501,000 in the three month period ended March 31, 2002 from $1,157,000 in the three month period ended March 31, 2001 and increased $3,548,000, or 161%, to $5,746,000 in the six month period ended March 31, 2002 from $2,198,000 in the

six month period ended March 31, 2001. These increases are primarily due to expenses incurred by the Company for its Phase III clinical trial for trospium which commenced in September 2001. Additionally, noncash expense related to a stock option grant and modifications of stock option grants was offset by reduced development costs related to PRO 2000 as certain stability programs ended. Total research and development costs for the three month period ended March 31, 2002 substantially relate to the Company's major compounds currently being developed as follows: trospium $2,114,000, PRO 2000 $191,000, and dersalazine $176,000.

General and administrative expense increased $518,000, or 25%, to $2,605,000 in the three month period ended March 31, 2002 from $2,087,000 in the three month period ended March 31, 2001 and increased $485,000, or 13%, to $4,183,000 in the six month period ended March 31, 2002 from $3,698,000 in the six month period ended March 31, 2001. These increases are primarily due to noncash expense related to modifications of stock option grants partially offset by the absence of legal and consulting fees relating to the Company's former suit against American Home Products Corporation ("AHP", now Wyeth).



The product withdrawal credit of $618,000 reflected in the three and six month periods ended March 31, 2001 relates to the insurance reimbursement of certain Redux-related costs included in an insurance claim payment received by the Company in January 2001.

Investment income decreased $268,000, or 47%, to $298,000 in the three month period ended March 31, 2002 from $566,000 in the three month period ended March 31, 2001 and decreased $547,000, or 51%, to $526,000 in the six month period ended March 31, 2002 from $1,073,000 in the six month period ended March 31, 2001. Despite higher average invested cash balances, these decreases resulted from substantially reduced market interest rates for the fiscal 2002 periods compared to the fiscal 2001 periods.

The charge for the cumulative effect of the change in accounting principle of $10,000,000 in the six month period ended March 31, 2001 is related to the Company's adoption in fiscal 2001 of the SEC's Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements."

For the three month period ended March 31, 2002, the Company had a net loss of $(4,808,000), or $(0.10) per share, diluted, compared to net loss of $(1,885,000), or $(0.04) per share, diluted, for the three month period ended March 31, 2001. For the six month period ended March 31, 2002, the Company had a net loss of $(6,754,000), or $(0.15) per share, diluted, compared to a net loss of $(13,742,000), or $(0.32) per share, diluted, for the six month period ended March 31, 2001. The Company expects to report losses for its consolidated operations for fiscal 2002.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At March 31, 2002, the Company had consolidated cash, cash equivalents and marketable securities of $50,018,000 compared to $32,171,000 at September 30, 2001. This increase of $17,847,000 is primarily due to receipt of approximately $23,300,000 of net proceeds from the Company's December 2001 private placement of 3,125,000 shares of Common Stock, offset primarily by $6,083,000 of cash used in operating activities.

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 development, including its on-going Phase III trial, regulatory and pre-marketing activities for trospium. There can be no assurance that results of any on-going 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.

Total research and development costs incurred by the Company through March 31, 2002 on the major compounds currently being developed, except pagoclone, including allocation of corporate general and administrative expenses, are approximately as follows: trospium $17,300,000, PRO 2000 $5,700,000, and dersalazine $900,000. Pfizer has full contractual responsibility for all pagoclone development costs. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the U.S. Food and Drug Administration which could necessitate additional and unexpected clinical



trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government- or agency-sponsored studies that could reduce the Company's development costs. In the event the Company were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs incurred by the Company could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other risks, variables and considerations related to each compound and regulatory uncertainties in general, the Company estimates research and development costs, excluding allocation of corporate general and administrative expenses, through the preparation of an NDA for its major compounds currently being developed as follows: approximately $9,000,000 for trospium, approximately $15,000,000 for PRO 2000 and approximately $38,000,000 for dersalazine. The Company cannot reasonably estimate date of completion for any compound that is not at least in

Phase III clinical development due to the uncertainty of the number of required trials and size of such trials and the duration of development. The Company estimates that it will file an NDA for trospium by the end of 2002. Actual costs and time to complete may differ significantly from the estimates.

Analysis of Cash Flows

Cash used in operating activities during fiscal 2002 of $6,083,000 consisted primarily of the net loss of $(6,754,000), noncash compensation related to stock option grants and modifications of stock options and a net reduction of accrued expenses and other liabilities.

Cash used in investing activities in fiscal 2002 of $16,468,000 consisted primarily of net outflows from purchases of marketable securities.

Cash provided by financing activities in fiscal 2002 of $24,013,000 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 March 31, 2002, the Company had an outstanding insurance claim of approximately $3,660,000, which the Company paid through March 31, 2002 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").

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 claim 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 March 31, 2002. There can be no assurance that the Company will collect any of the $3,660,000 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.



Commitments and Contingencies

Below are the Company's future minimum payments under non-cancellable lease arrangements as of September 30, 2001:

| Fiscal Year | Operating Leases |
|---|---|
| 2002 | $ 470,000 |
| 2003 | 534,000 |
| 2004 | 536,000 |
| 2005 | 553,000 |
| 2006 | 568,000 |

| | |
|---|---|
| Thereafter | 313,000 |
| Total lease payments | $2,974,000 |

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 will thus be adopted by the Company as required, in fiscal year 2003. The Company does not expect the adoption of SFAS No. 141 and SFAS No. 142 to have a material effect on the Company's financial condition or results of operations.

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

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

Interest Rate Risk

Indevus 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. Indevus' investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity. Also, Indevus has implemented guidelines limiting the duration of its investments. Due to the conservative nature of these instruments, Indevus 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 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 Indevus 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 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 Indevus 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 has been transferred to the U.S. District Court for the District of Massachusetts. 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 Indevus 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.

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.

## Item 4. Submission of Matters to a Vote of Security Holders

The Company's annual meeting of stockholders was held on April 2, 2002. At the meeting (i) all seven director nominees were elected; (ii) the amendment of the Company's Restated Certificate of Incorporation, as amended, to change the name of the Company from "Interneuron Pharmaceuticals, Inc." to "Indevus Pharmaceuticals, Inc." was approved; (iii) the amendment of the Company's Restated Certificate of Incorporation, as amended, to delete certain restrictive covenants relating to the Company's Series B Preferred Stock was approved; (iv) the amendment to the Company's 2000 Stock Option Plan increasing the number of shares reserved for issuance thereunder from 2,500,000 shares to 3,500,000 shares was approved; and (v) the appointment of PricewaterhouseCoopers LLP as the Company's independent auditors was ratified.

(i) The following Directors were elected for a one-year term by the votes indicated:

Glenn L. Cooper, M.D., 38,121,495 for, 2,838,850 against; Harry J. Gray, 35,696,220 for, 5,264,125 against; Alexander M. Haig, Jr., 40,595,286 for, 365,059 against; Malcolm Morville, Ph.D., 40,820,382 for, 139,963 against;

Lindsay A. Rosenwald, M.D., 40,635,177 for, 325,168 against; Lee J. Schroeder, 35,697,957 for, 5,262,388 against; and David B. Sharrock, 40,443,824 for, 516,521 against.

(ii) The amendment of the Company's Restated Certificate of Incorporation, as amended, to change the name of the Company from "Interneuron Pharmaceuticals, Inc." to "Indevus Pharmaceuticals, Inc." was approved by a vote of 41,211,387 for, 321,726 against, and 49,453 abstaining.

(iii) The amendment of the Company's Restated Certificate of Incorporation, as amended, to delete certain restrictive covenants relating to the Company's Series B Preferred Stock was approved by a vote of 26,756,192 for, 311,600 against, and 153,318 abstaining.

(iv) The amendment to the Company's 2000 Stock Option Plan increasing the number of shares reserved for issuance thereunder from 2,500,000 shares to 3,500,000 shares was approved by a vote of 31,858,208 for, 9,617,145 against, and 107,213 abstaining.

(v) The appointment of PricewaterhouseCoopers LLP was ratified by a vote of 41,263,908 for, 277,584 against, and 41,075 abstaining.



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

(a) Exhibits

None

(b) Reports on Form 8-K

On January 3, 2002, the Company filed a report on Form 8-K reporting it had closed a private placement of 3,125,000 shares of the Company's Common Stock to a group of institutional investors and their affiliates at a price of $8.00 per share which resulted in $25,000,000 of gross proceeds to the Company.



## 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.

INDEVUS PHARMACEUTICALS, INC.

Date: May 14, 2002 By: /s/ Glenn L. Cooper, M.D.

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

Date: May 14, 2002 By: /s/ Michael W. Rogers

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

Date: May 14, 2002

By: /s/ Dale Ritter

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