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INDEVUS PHARMACEUTICALS INC

Form 10-Q

February 14, 2003

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2002, or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 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  
(State or other jurisdiction of  
incorporation or organization)

04-3047911  
(I.R.S. Employer  
Identification Number)

One Ledgeмонт 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

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 such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes

No

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

Class:  
Common Stock \$.001 par value

Outstanding at February 13, 2003:  
46,875,885 shares

INDEVUS PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

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Item 1. Financial Statements

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

	ASSETS	December 31, 2002	September 30 2002
		-----	-----
Current assets:			
Cash and cash equivalents		\$ 16,224	\$ 19,977
Marketable securities		19,877	20,516
Accounts receivable		63	550
Prepays and other current assets		991	533
		-----	-----
Total current assets		37,155	41,576
Marketable securities		-	1,050
Equity securities		22	31
Insurance claim receivable		1,258	1,258
Property and equipment, net		22	16
		-----	-----
Total assets		\$ 38,457	\$ 43,931
		=====	=====

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LIABILITIES

Current liabilities:		
Accounts payable	\$ 813	\$ 350
Accrued expenses	5,859	6,326
Deferred revenue	-	24
	-----	-----
Total current liabilities	6,672	6,700
Minority interest	13	13

STOCKHOLDERS' EQUITY

Preferred stock, \$.001 par value, 5,000,000 shares authorized; Series B, 239,425 shares issued and outstanding (liquidation preference at December 31, 2002 \$3,034);	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at December 31, 2002 \$503)	500	500
Common stock, \$.001 par value, 80,000,000 shares authorized; 46,875,885 shares issued and outstanding at December 31 and September 30, 2002	47	47
Additional paid-in capital	302,669	302,678
Accumulated deficit	(274,310)	(268,879)
Accumulated other comprehensive loss	(134)	(128)
	-----	-----
Total stockholders' equity	31,772	37,218
	-----	-----
Total liabilities and stockholders' equity	\$ 38,457	\$ 43,931
	=====	=====

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

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

	Three months ended December 31,	
	2002	2001
	-----	-----
Revenues:		
Royalties	\$ -	\$ 3,199
Contract and license fees	822	342
	-----	-----
Total revenues	822	3,541
Costs and expenses:		
Cost of revenues	210	838
Research and development	3,777	3,245

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General and administrative	2,457	1,578
	-----	-----
Total costs and expenses	6,444	5,661
	-----	-----
Loss from operations	(5,622)	(2,120)
Investment income, net	191	228
Minority interest	-	(54)
	-----	-----
Net loss	\$ (5,431)	\$ (1,946)
	=====	=====
Net loss per common share:		
Basic and diluted	\$ (0.12)	\$ (0.04)
	=====	=====
Weighted average common shares outstanding:		
Basic and diluted	46,876	43,659
	=====	=====

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

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

	Three months
	-----
	2002
	-----
Cash flows from operating activities:	
Net loss	\$ (5,431)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	4
Minority interest in net loss of consolidated subsidiary	-
Noncash compensation	-
Change in assets and liabilities:	
Accounts receivable	487
Prepaid and other assets	(458)
Accounts payable	463
Accrued expenses and other liabilities	(501)
	-----
Net cash used in operating activities	(5,436)
	-----
Cash flows from investing activities:	
Capital expenditures	(10)
Purchase of marketable securities	(2,689)

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Proceeds from maturities and sales of marketable securities	4,382
	-----
Net cash provided by (used in) investing activities	1,683
	-----
Cash flows from financing activities:	
Net proceeds from issuance of common stock	-
Distribution to minority interest stockholder	-
	-----
Net cash provided by financing activities	-
	-----
Net change in cash and cash equivalents	(3,753)
Cash and cash equivalents at beginning of period	19,977
	-----
Cash and cash equivalents at end of period	\$ 16,224
	=====

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

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### 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, 2002.

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 December 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 9,571,786 shares of Common Stock at exercise prices ranging from \$2.00 to \$20.13 with expiration dates ranging up to May 13, 2012; and (ii) warrants to purchase 105,000 shares of Common Stock with exercise prices ranging from \$5.00 to \$7.13 and with expiration dates ranging up to July

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17, 2006. Additionally, during the three month period ended December 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 585,739 shares of Common Stock at exercise prices ranging from \$1.22 to \$1.88 and expiration dates ranging up to October 8, 2012; and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

During the three month period ended December 31, 2001, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period, were as follows: (i) options to purchase 139,565 shares of Common Stock at exercise prices ranging from \$8.37 to \$20.13 with expiration dates ranging up to December 5, 2011; and (ii) warrants to purchase 550,000 shares of Common Stock with exercise prices ranging from \$7.88 to \$10.00 and with expiration dates ranging up to June 1, 2002. Additionally, during the three month period ended December 31, 2001, securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 9,394,165 shares of Common Stock at exercise prices ranging from \$1.47 to \$7.25 and expiration dates ranging up to November 26, 2011; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; (iii) warrants to purchase 130,000 shares of Common Stock at exercise prices ranging from \$5.00 to \$7.13 and expiration dates ranging up to July 17, 2006; and (iv) unvested Restricted Stock Awards of 225,000 shares of Common Stock granted pursuant to the Company's 1997 Equity Incentive Plan.

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### C. Comprehensive Loss

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

	Three Months Ended December 31,	
	2002	2001
Net loss	\$(5,431,000)	\$(1,946,000)
Change in unrealized net gain or loss on investments	(6,000)	(124,000)
Comprehensive loss	\$(5,437,000)	\$(2,070,000)

### D. Agreement

In December 2002, the Company entered into an amended agreement with Eli Lilly and Company ("Lilly") providing for Lilly to pay the Company (i) an initial payment of approximately \$777,000, (ii) royalties on net sales of Sarafem commencing October 1, 2002 through the expiration of the Company's patent related to Sarafem, and (iii) milestones based on Lilly's achievement of certain levels of Sarafem sales in each quarter commencing January 1, 2003, subject to an aggregate cap and immediate acceleration upon Lilly's sublicense of its rights related to Sarafem. The Company recognized the \$777,000 initial

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payment as revenue upon signing the renegotiated agreement because the Company has no continuing performance obligations under the contract. Massachusetts Institute of Technology ("MIT"), our licensor, is entitled to a portion of payments made to Indevus by Lilly.

### E. Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") 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 are effective for fiscal years beginning after December 15, 2001. The Company's adoption of SFAS Nos. 141 and 142 in fiscal year 2003 did not 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 supercedes 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 are effective for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The Company's adoption of SFAS No. 144 in fiscal year 2003 did not have a material effect on its financial position or results of operations.

In September 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," ("SFAS No. 146") which supersedes Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs incurred in a Restructuring)." The standard affects the accounting for restructuring charges and related

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activities. The provisions of this statement are required to be adopted for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect the adoption of SFAS No. 146 to have an impact on its financial position and results of operations.

In July 2000, the EITF released EITF 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21") for comment. EITF 00-21 addresses revenue recognition for arrangements with multiple deliverables. The draft of EITF 00-21 was approved in November 2002 and is effective for revenue arrangements entered into in fiscal years beginning after June 15, 2003, with early adoption permitted. The impact of EITF 00-21 on the Company's financial statements has not yet been determined.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure -- an amendment of SFAS 123" ("SFAS No. 148"). SFAS No. 148 provides additional transition guidance for companies that elect to voluntarily adopt the accounting provisions of SFAS No. 123,

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"Accounting for Stock-Based Compensation" ("SFAS No. 123") and is intended to encourage the adoption of the accounting provisions of SFAS No. 123. Under the provisions of SFAS No. 148, companies that choose to adopt the accounting provisions of SFAS 123 will be permitted to select from three transition methods: the prospective method, the modified prospective method and the retroactive restatement method. SFAS No. 148 requires certain new disclosures that are incremental to those required by SFAS No.123, which must also be made in interim financial statements. The transition and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The impact on the Company's financial statements has not yet been determined.

### 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 SEC, 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, including trospium; its ability to enter into corporate collaborations or to 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 predict 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, 2002. These factors include, but are not limited to: dependence on the success of trospium; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of the Company's products; risks associated with contractual arrangements; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners; history of operating losses and expectation of future losses; product liability; risks related to certain insurance-related litigation; risks relating to the Redux-related litigation; limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; and other risks. The forward-looking statements represent the Company's judgment 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, 2002. Unless the context indicates otherwise, "Indevus" or the "Company" refer to Indevus Pharmaceuticals, Inc.

#### General

#### Description of the Company



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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 five core compounds: trospium for overactive bladder, pagoclone for panic and generalized anxiety disorders, citicoline for ischemic stroke, IP 751 for pain and inflammatory disorders, and PRO 2000 for the prevention of infection by HIV and other sexually transmitted pathogens.

### Major Products

Trospium is a muscarinic receptor antagonist in development as a treatment for overactive bladder. In September 2002, the Company announced that a 523-patient, double-blind, placebo-controlled Phase III clinical trial with trospium met both of its primary endpoints and all of its overactive bladder secondary endpoints. Based on the results of this Phase III trial and the European clinical trials database, the Company plans to file a new drug application ("NDA") for trospium during the second calendar quarter of 2003, contingent upon discussions with the U.S. Food and Drug Administration ("FDA"). The Company is evaluating commercial opportunities for the drug. As of December 16, 2002, the Company entered into a manufacturing agreement with Madaus AG ("Madaus"), licensor of trospium to the Company, whereby Madaus will produce and sell to the Company commercial quantities of trospium in bulk form. The agreement provides for certain minimum purchases commencing in the year trospium is first sold commercially.

Pagoclone is a novel GABA (gamma amino butyric acid) receptor agonist in development for the treatment of anxiety disorders. The Company is pursuing a new worldwide development partnership for the commercialization of pagoclone.

Citicoline has been under development by the Company as a neuroprotective treatment for ischemic stroke. Indevus has signed a non-binding memorandum of agreement with a privately held biotechnology company to fund the further development of citicoline. The finalization of this agreement is contingent upon input from the FDA on the design and clinical endpoints of an additional large Phase III trial and the negotiation of a definitive contract.

IP 751 is a compound in early clinical development to treat pain and inflammatory disorders. In December 2002, the Company announced results of a Phase II clinical trial in Germany showing that treatment with IP 751 significantly reduced neuropathic pain, with no significant adverse events and psychoactive properties. An investigative new drug application ("IND") for IP 751 has been filed with the FDA, and an initial Phase I clinical trial designed to assess its safety showed that it was well tolerated, with no clinically significant adverse events and no evidence of psychotropic activity. The Company is currently determining the optimal clinical and regulatory plan for advancing this compound as a therapy for pain and inflammatory disorders.

PRO 2000 is a topical microbicide in development for the prevention of the sexual transmission of HIV and other sexually-transmitted pathogens. A number of clinical trials are ongoing or planned. These trials include a European Commission-funded Phase II safety trial in at-risk African women planned to begin in early 2003. The Company will owe its PRO 2000 licensor a \$500,000 milestone payment subsequent to the initiation of this trial. In addition, an National Institutes of Health-sponsored Phase II/III pivotal trial to determine the safety and efficacy of PRO 2000 in blocking male to female HIV transmission is planned to begin in 2003 in Africa and India. The study is expected to involve approximately 10,000 HIV-uninfected women at risk for acquiring HIV by virtue of living in countries where the risk of such infection is high.

The Company licensed to Lilly exclusive, worldwide rights to Indevus' patent covering the use of fluoxetine to treat certain conditions and symptoms

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associated with premenstrual syndrome. Lilly is marketing the drug under the trade name Sarafem. The Company received royalties based on net sales of Sarafem through December 2001. In

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December 2002, the Company entered into an amended licensing agreement with Lilly providing for a \$777,000 initial payment to the Company upon the signing of the agreement and royalty payments from Lilly to the Company based on net sales of Sarafem in the U.S. from October 1, 2002 until the expiration of the Company's patent. In addition, the agreement includes other potential milestone payments to the Company from Lilly. On January 23, 2003, Galen Holdings PLC announced the completion of its acquisition of the U.S. sales and marketing rights to Sarafem from Lilly. Pursuant to our agreement with Lilly, the remaining milestone payments of \$2,184,000 were accelerated and received by the Company from Lilly in February 2003. MIT, the Company's licensor, is entitled to a portion of payments made to Indevus by Lilly.

### Critical Accounting Policies and Significant Judgments and Estimates

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 U.S. 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.

### Critical Accounting Policies

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, 2002, 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.

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The terms of the agreements typically include non-refundable license fees,

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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.

### Significant Judgments and Estimates

#### Insurance Claim Receivable

As of December 31, 2002, the Company had an outstanding insurance claim of approximately \$3,735,000, including \$3,688,000 of which the Company paid through December 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"), which is in liquidation proceedings. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available facts and circumstances. The Company believes its reserve of \$2,477,000 against the \$3,735,000 of insurance claims on Reliance as of December 31, 2002 is a significant estimate reflecting management's judgement. To the extent the Company does not collect the insurance claim receivable of \$1,258,000, the Company would be required to record additional charges. Alternatively, if the Company collects amounts in excess of the current receivable balance, the Company would record a credit for the additional funds received in the statement of operations.

#### Redux-Related Liabilities

The Company also has an accrued liability of \$1,242,000 for Redux-related expenses, including legal expenses. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at December 31, 2002. To the extent the amounts paid differ from the amounts accrued, the

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Company will record a charge or credit to the statement of operations.

### Results of Operations

Total revenues decreased to \$822,000 in the three month period ended December 31, 2002 from \$3,541,000 in

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the three month period ended December 31, 2001. Contract and license fee revenue of \$822,000 in the first quarter of fiscal 2003 consisted primarily of \$777,000 from an initial payment received from Lilly related to the amended agreement for Sarafem. Contract and license fee revenue of \$342,000 in the first quarter of fiscal 2002 consisted primarily of revenue from a research grant related to certain PRO 2000 development costs. Royalty revenue of \$3,199,000 in the first quarter of fiscal 2002 related to royalties received from Lilly related to sales of Sarafem. Pursuant to its amended agreement, the Company expects to commence receiving royalties from Lilly on sales of Sarafem in the second quarter of fiscal 2003.

Cost of revenues of \$210,000 and \$838,000 in the three month periods ended December 31, 2002 and 2001, respectively, consisted primarily of amounts due to MIT for their portion of the contractual payments and royalties received from Lilly.

Research and development expense increased \$532,000, or 16%, to \$3,777,000 in the three month period ended December 31, 2002 from \$3,245,000 in the three month period ended December 31, 2001. This increase is primarily due to expenses incurred by the Company related to the development of, and preparation of an NDA for, tropsium.

General and administrative expense increased \$879,000, or 56%, to \$2,457,000 in the three month period ended December 31, 2002 from \$1,578,000 in the three month period ended December 31, 2001. This increase was primarily due to increased pre-marketing costs related to tropsium and increased legal costs related to the litigation with Columbia Casualty Company ("CNA"). In February 2003, CNA and the Company agreed to withdraw their respective claims against each other and end the litigation.

Investment income decreased \$37,000, or 16%, to \$191,000 in the three month period ended December 31, 2002 from \$228,000 in the three month period ended December 31, 2001. This decrease resulted from reduced market interest rates on higher weighted average invested cash balances.

For the three month period ended December 31, 2002, the Company had a net loss of \$5,431,000, or \$(0.12) per share, basic and diluted, compared to a net loss of \$1,946,000, or \$(0.04) per share, basic and diluted, for the three month period ended December 31, 2001. The Company expects to report losses for its consolidated operations for fiscal 2003.

### Liquidity and Capital Resources

#### Cash, Cash Equivalents and Marketable Securities

At December 31, 2002, the Company had consolidated cash, cash equivalents and marketable securities of \$36,101,000 compared to \$41,543,000 at September 30, 2002. This decrease of \$5,442,000 primarily represents cash used in operating activities.

The Company believes it has sufficient cash for currently planned

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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 on acceptable terms, or at all.

### 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 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

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a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with current Good Manufacturing Practices ("cGMP") 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. The Company expects to expend a substantial amount during the next twelve months to fund development, regulatory and pre-marketing activities for trospium.

The Company expects to rely on Madaus to manufacture trospium for commercial use. The Company believes that Madaus' manufacturing facility for trospium does not currently meet cGMP requirements. Although Madaus is endeavoring to bring its manufacturing facility into compliance with cGMP requirements, failure to do so in a timely manner could cause a material delay in the NDA submission, FDA approval, if any, and commercialization of trospium. While the Company may seek a second source for trospium if Madaus is unable to meet all regulatory requirements or provide the necessary quantities of trospium in a timely manner, this could also cause a material delay in the NDA submission, FDA approval, if any, and commercialization of trospium.

Total research and development expenses incurred by the Company through December 31, 2002 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: trospium \$29,800,000, pagoclone \$15,700,000, citicoline \$77,000,000, PRO 2000 \$6,800,000, and IP 751 \$600,000. In June 2002, the Company re-acquired rights to pagoclone from Pfizer. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. 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 FDA 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 to be 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

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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 remaining research and development costs, excluding allocation of corporate general and administrative expenses, from December 31, 2002 through the preparation of an NDA for its major compounds currently being developed as follows: approximately \$4,000,000 for trospium, approximately \$15,000,000 for PRO 2000 and, approximately \$40,000,000 for pagoclone. The Company does not plan to develop citicoline further without project-specific funding. 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. Actual costs and time to complete may differ significantly from the estimates.

### Analysis of Cash Flows

Cash used in operating activities during the three month period ended December 31, 2002 of \$5,436,000 consisted primarily of the net loss of \$5,431,000.

Cash provided by investing activities during the three month period ended December 31, 2002 of \$1,683,000 consisted primarily of \$1,693,000 of net inflows from maturities and sales of marketable securities.

### Commitments and Contingencies

At September 30, 2002, the Company's future minimum payments under non-cancelable lease arrangements are as follows:

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Fiscal Year -----	Operating Leases -----
2003 .....	\$ 543,000
2004 .....	560,000
2005 .....	555,000
2006 .....	568,000
2007 .....	312,000
Thereafter .....	-
	-----
Total lease payments .....	\$2,538,000 =====

Pursuant to certain of the Company's in-licensing arrangements, the Company will owe payments to its licensors upon achievement of certain development and regulatory milestones; the Company cannot predict if or when such events will occur.

### 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

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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 are effective for fiscal years beginning after December 15, 2001. The Company's adoption of SFAS Nos. 141 and 142 in fiscal year 2003 did not 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 supercedes 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 are effective for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The Company's adoption of SFAS No. 144 in fiscal year 2003 did not have a material effect on its financial position or results of operations.

In September 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," ("SFAS No. 146") which supersedes Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs incurred in a Restructuring)." The standard affects the accounting for restructuring charges and related activities. The provisions of this statement are required to be adopted for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect the adoption of SFAS No. 146 to have an impact on its financial position and results of operations.

In July 2000, the EITF released EITF 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21") for comment. EITF 00-21 addresses revenue recognition for arrangements with multiple deliverables. The draft of EITF 00-21 was approved in November 2002 and is effective for revenue arrangements entered into in fiscal years beginning after June 15, 2003, with early adoption permitted. The impact of EITF 00-21 on the Company's financial statements has not yet been determined.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition

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and Disclosure -- an amendment of SFAS 123" ("SFAS No. 148"). SFAS No. 148 provides additional transition guidance for companies that elect to voluntarily adopt the accounting provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123") and is intended to encourage the adoption of the accounting provisions of SFAS No. 123. Under the provisions of SFAS No. 148, companies that choose to adopt the accounting provisions of SFAS 123 will be permitted to select from three transition methods: the prospective method, the modified prospective method and the retroactive restatement method. SFAS No. 148 requires certain new disclosures that are incremental to those required by SFAS No.123, which must also be made in interim financial statements. The transition and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The impact on the Company's financial statements has not yet been determined.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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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.

### Item 4. Controls and Procedures

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective for the purpose of timely alerting the appropriate individuals of the material information required to be included in our periodic SEC reports. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of our last evaluation.

## PART II. Other Information

### Item 1. Legal Proceedings

**Product Liability Litigation:** Subsequent to the market withdrawal of Redux in September 1997, the Company had 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-



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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, PPH, 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 Wyeth 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 Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth 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 Wyeth 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 Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth's national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

**Complaint Against Wyeth:** On January 24, 2000, the Company announced it had filed a complaint against Wyeth 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 Wyeth's knowing and willful deceptive acts and practices, fraud and misrepresentations and breach of contract. Wyeth filed an answer denying the allegations of such complaint. Pursuant to the AHP Indemnity and Release Agreement, described above, such complaint was dismissed on June 28, 2001.

**Insurance Litigation:** In February 2003, CNA agreed to dismiss, with prejudice, its lawsuit against the Company and the Company in turn agreed to dismiss, with prejudice, its claims against CNA, without costs or fees to either side. In August 2001, CNA, 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 was 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 CNA had paid to the Company under its

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insurance policy. CNA alleged that under the policy it was subrogated to any claim for indemnification that Indevus may have had against Wyeth related to Redux and that such claim was compromised without its consent when the Company entered into the AHP Indemnity and Release Agreement. On March 8, 2002, the Company filed an Answer, Affirmative Defenses and Counterclaims to the action, including counterclaims for breach of contract, breach of the implied covenant of good faith and fair dealing, declaratory judgment pursuant to 28 U.S.C. Sections 2201 and 2202, and unfair or deceptive acts and/or unfair claims settlement practices.

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General: Pursuant to agreements between the parties, under certain circumstances, the Company may be required to indemnify Servier, Boehringer 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. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

#### (a) Exhibits

- 10.128 Amendment No.1 to Licensing Agreement by and between Eli Lilly and Company, Eli Lilly S.A., and Indevus Pharmaceuticals, Inc. effective as of October 1, 2002 (1)
- 10.129 Supply Agreement as of December 16, 2002 by and between Madaus AG and Indevus Pharmaceuticals, Inc. (1)
- 99.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer
- 99.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer

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(1) Confidential treatment requested for a portion of this Exhibit

(b) Reports on Form 8-K

The Company did not file any reports on Form 8-K in the three month period ended December 31, 2002.

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### 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: February 14, 2003

By: /s/ Glenn L. Cooper

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

Date: February 14, 2003

By: /s/ Michael W. Rogers

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

Date: February 14, 2003

By: /s/ Dale Ritter

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

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### CERTIFICATION PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14 AND 15d-14, AS PROMULGATED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Glenn L. Cooper, Chief Executive Officer of Indevus Pharmaceuticals, Inc. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Indevus Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

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4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the issuer and have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report was being prepared;
  - (b) evaluated the effectiveness of the issuer's disclosure controls and procedures as of a date within 90 days prior to the filing date of this report ("Evaluation Date"); and
  - (c) presented in this report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation, to the issuer's auditors and the audit committee of the board of directors:
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
6. The issuer's other certifying officer and I have indicated in this report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

By: /s/ Glenn L. Cooper

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Chief Executive Officer  
February 14, 2003

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CERTIFICATION PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14 AND 15d-14,  
AS PROMULGATED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael W. Rogers, Chief Financial Officer of Indevus Pharmaceuticals, Inc. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Indevus Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this

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report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;
4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the issuer and have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report was being prepared;
  - (b) evaluated the effectiveness of the issuer's disclosure controls and procedures as of a date within 90 days prior to the filing date of this report ("Evaluation Date"); and
  - (c) presented in this report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation, to the issuer's auditors and the audit committee of the board of directors:
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
6. The issuer's other certifying officer and I have indicated in this report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

By: /s/ Michael W. Rogers

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Chief Financial Officer  
February 14, 2003