

INDEVUS PHARMACEUTICALS INC
Form 10-Q
August 13, 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 June 30, 2003, or

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

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 Ledgemont Center
99 Hayden Avenue
Lexington, Massachusetts
(Address of principal executive offices)

02421-7966
(Zip Code)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 by check mark whether the registrant is an accelerated filer (as defined in Rule 12(b)-2 of the Exchange Act.)

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:	Outstanding at August 12, 2003
Common Stock \$.001 par value	47,041,360 shares

INDEVUS PHARMACEUTICALS, INC.

INDEX TO FORM 10-Q

	PAGE
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
<u>Consolidated Balance Sheets</u> as of June 30, 2003 and September 30, 2002	3
<u>Consolidated Statements of Operations</u> for the Three and Nine Months ended June 30, 2003 and 2002	4
<u>Consolidated Statements of Cash Flows</u> for the Nine Months ended June 30, 2003 and 2002	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	17
Item 4. <u>Controls and Procedures</u>	18
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	18
Item 6. <u>Exhibits and Reports on Form 8-K</u>	19
<u>SIGNATURES</u>	20

Item 1. Financial Statements**INDEVUS PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)****(Amounts in thousands except share data)****ASSETS**

	June 30, 2003	September 30, 2002
	<u> </u>	<u> </u>
Current assets:		
Cash and cash equivalents	\$ 17,554	\$ 19,977
Marketable securities	6,933	20,516
Accounts receivable	74	550
Prepays and other current assets	1,267	533
	<u> </u>	<u> </u>
Total current assets	25,828	41,576
Marketable securities		1,050
Equity securities	58	31
Insurance claim receivable	1,258	1,258
Property and equipment, net	19	16
	<u> </u>	<u> </u>
Total assets	<u>\$ 27,163</u>	<u>\$ 43,931</u>

LIABILITIES

Current liabilities:		
Accounts payable	\$ 1,193	\$ 350
Accrued expenses	9,113	6,326
Deferred revenue		24
	<u> </u>	<u> </u>
Total current liabilities	10,306	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 June 30, 2003 \$3,019);	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at June 30, 2003 \$500)	500	500
Common stock, \$.001 par value, 80,000,000 shares authorized; 46,937,193 and 46,875,885 shares issued and outstanding at June 30, 2003 and September 30, 2002, respectively	47	47
Additional paid-in capital	302,753	302,678
Accumulated deficit	(289,326)	(268,879)
Accumulated other comprehensive loss	(130)	(128)
	<u> </u>	<u> </u>

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Total stockholders' equity	16,844	37,218
Total liabilities and stockholders' equity	\$ 27,163	\$ 43,931

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

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For the three and nine months ended June 30, 2003 and 2002

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended June 30,		Nine months ended June 30,	
	2003	2002	2003	2002
Revenues:				
Royalty revenue	\$ 702	\$ 226	\$ 3,559	\$ 3,439
Contract and license fees	12	2	848	416
Total revenues	714	228	4,407	3,855
Costs and expenses:				
Cost of revenues	169	55	975	978
Research and development	8,718	4,210	15,735	9,957
Marketing, general and administrative	3,976	1,724	8,593	5,907
Total costs and expenses	12,863	5,989	25,303	16,842
Loss from operations	(12,149)	(5,761)	(20,896)	(12,987)
Investment income, net	99	234	449	760
Impairment of equity securities		(487)		(487)
Minority interest		(1)		(55)
Net loss	\$ (12,050)	\$ (6,015)	\$ (20,447)	\$ (12,769)
Net loss per common share:				
Basic and diluted	\$ (.26)	\$ (0.13)	\$ (0.44)	\$ (0.28)
Weighted average common shares outstanding:				
Basic and diluted	46,890	46,431	46,882	45,583

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

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended June 30, 2003 and 2002

(Unaudited)

(Amounts in thousands)

	Nine months ended June 30,	
	2003	2002
Cash flows from operating activities:		
Net loss	\$ (20,447)	\$ (12,769)
Adjustments to reconcile net loss to net cash used in operating activities:		
Deprecation and amortization	12	53
Minority interest in net income of consolidated subsidiary		55
Impairment of equity securities		487
Noncash compensation		2,190
Change in assets and liabilities:		
Accounts receivable	476	234
Prepaid and other assets	(734)	(115)
Accounts payable	843	446
Accrued expenses and other liabilities	2,771	(311)
Net cash used in operating activities	<u>(17,079)</u>	<u>(9,730)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(3,877)	(22,126)
Proceeds from maturities and sales of marketable securities	18,482	5,994
Capital expenditures	(15)	(8)
Net cash provided by (used in) investing activities	<u>14,590</u>	<u>(16,140)</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock	66	24,051
Distribution to minority interest stockholder		(54)
Net cash provided by financing activities	<u>66</u>	<u>23,997</u>
Net change in cash and cash equivalents	(2,423)	(1,873)
Cash and cash equivalents at beginning of period	19,977	24,923
Cash and cash equivalents at end of period	<u>\$ 17,554</u>	<u>\$ 23,050</u>

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, 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 June 30, 2003, 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 3,528,686 shares of Common Stock at prices ranging from \$4.63 to \$20.13 with expiration dates ranging up to June 3, 2013; 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 17, 2006. Additionally, during the three month period ended June 30, 2003, 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 7,008,097 shares of Common Stock at prices ranging from \$1.22 to \$4.40 with expiration dates ranging up to April 23, 2013; and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

During the three month period ended June 30, 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 3,215,431 shares of Common Stock at prices ranging from \$6.00 to \$20.13 with expiration dates ranging up to May 13, 2012; and (ii) warrants to purchase 560,000 shares of Common Stock with exercise prices ranging from \$6.19 to \$12.77 and with expiration dates ranging up to July 17, 2006. Additionally, during the three month period ended June 30, 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 6,647,949 shares of Common Stock at prices ranging from \$1.22 to \$5.00 with expiration dates ranging up to June 14, 2012; (ii) warrants to purchase 55,000 shares of Common Stock with exercise prices ranging from \$5.00 to \$5.13 and with expiration dates ranging up to February 3, 2005; (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 nine month period ended June 30, 2003, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) options to purchase 6,444,883 shares of Common Stock at prices ranging from \$3.13 to \$20.13 with expiration dates ranging up to April 23, 2013; 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 17, 2006. Additionally, during the

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

nine month period ended June 30, 2003, 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 3,836,639 shares of Common Stock at prices ranging from \$1.22 to \$2.38 with expiration dates ranging up to March 12, 2013; and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

During the nine month period ended June 30, 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 255,604 shares of Common Stock at prices ranging from \$7.88 to \$20.13 with expiration dates ranging up to April 8, 2012; and (ii) a warrant to purchase 500,000 shares of Common Stock with an exercise price of \$9.44 and with an expiration date of July 12, 2002. Additionally, during the nine month period ended June 30, 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 9,474,023 shares of Common Stock at prices ranging from \$1.22 to \$7.25 with expiration dates ranging up to June 14, 2012; (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 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.

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. *Pro Forma Net Loss Information:*

The Company applies Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, in accounting for its stock-based compensation plans. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123 (SFAS No. 148). Had compensation expense for the Company's stock option plans been determined based on the fair value at the grant date for awards under these plans using a Black-Scholes option pricing model consistent with the methodology prescribed under SFAS No. 148, the Company's net loss and net loss per share would have approximated the pro forma amounts indicated below:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2003	2002	2003	2002
As reported net loss	\$ (12,050,000)	\$ (6,015,000)	\$ (20,447,000)	\$ (12,769,000)
Adjustment to compensation expense for stock-based awards	\$ (241,000)	\$ (240,000)	\$ (760,000)	\$ (1,734,000)
Pro forma net loss	\$ (12,291,000)	\$ (6,255,000)	\$ (21,207,000)	\$ (14,503,000)
As reported net loss per common share, basic and diluted	\$ (0.26)	\$ (0.13)	\$ (0.44)	\$ (0.28)
Pro forma net loss per common share, basic and diluted	\$ (0.26)	\$ (0.13)	\$ (0.45)	\$ (0.32)

D. *Comprehensive Loss*

Comprehensive loss for the three and nine month periods ended June 30, 2003 and 2002, respectively, is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2003	2002	2003	2002
Net loss	\$ (12,050,000)	\$ (6,015,000)	\$ (20,447,000)	\$ (12,769,000)
Change in unrealized net gain or loss on investments	30,000	408,000	(2,000)	12,000
Comprehensive loss	\$ (12,020,000)	\$ (5,607,000)	\$ (20,449,000)	\$ (12,757,000)

E. *Agreements*

In December 2002, the Company entered into a renegotiated 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 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.

In March 2003, the Company signed an exclusive development agreement with Shire Laboratories Inc. (Shire) under which Shire is developing extended release formulations of trespium. The agreement includes potential future development and commercialization milestone payments from Indevus to Shire, as well as royalties based on potential future sales of extended release trespium. Indevus will be responsible for all development costs and the commercialization of extended release formulations of trespium under this agreement.

On April 10, 2003, the Company amended the terms of the PRO 2000 licensing agreement with Paligent Inc., the successor company to Heavenly Door.com (Paligent) (the Paligent Agreement). Paligent agreed to relinquish a potential future \$500,000 milestone payment and provide Indevus an option to acquire all rights to PRO 2000 by a certain future date in exchange for an immediate payment and an optional buyout payment by Indevus. On April 23, 2003, the Company announced that it has licensed exclusive worldwide rights from Aventis SA (Aventis) to aminocandin, an anti-fungal compound for the treatment of systemic, invasive infections (the Aventis Agreement). In exchange for these rights and for Aventis' inventory of aminocandin, Indevus made an up-front payment to Aventis, and is obligated to pay potential milestones and royalties on potential future sales. Under the Aventis Agreement, Indevus is responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology. The Company charged research and development expense \$2,000,000 in the three month period ended June 30, 2003 for aggregate payments made pursuant to these agreements.

F. *Subsequent Event*

In July 2003, the Company received net proceeds of approximately \$68,600,000 from the sale of \$72,000,000 aggregate principal amount of 6.25% Convertible Senior Notes due 2008 (the Notes) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. This sale included the exercise by the initial purchasers of an option to purchase an additional \$12,000,000 aggregate principal

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

amount of the Notes. The Notes are convertible at anytime prior to the July 15, 2008 maturity date into the Company's Common Stock at an initial conversion price of \$6.656 per share, subject to adjustment for certain events; the Company has reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and agreed to file a registration statement with the SEC for such shares. Additionally, all or a portion of the Notes are redeemable by the Company for cash at any time after July 20, 2006 provided our Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period and all of the Notes are subject to repurchase by the Company at the option of the Note holders if a change in control occurs. Interest is payable semiannually in arrears on January 15 and July 15 through the maturity date.

G. *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 supercedes 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 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, 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 have been made in these interim financial statements. The Company does not intend to adopt the accounting provision of SFAS No. 123 in the fiscal year ending September 30, 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of ARB No. 51 (FIN 46). This interpretation addresses the consolidation of certain variable interest entities (VIE s) for which a controlling financial interest exists. FIN 46 applies immediately to financial interest obtained in VIEs after January 31, 2003. It applies in the first fiscal year or interim period beginning after June 15, 2003, to VIEs in which a financial interest was obtained before February 1, 2003. FIN 46 may be applied prospectively with a cumulative effect adjustment of by restating previously issued financial statements with a cumulative effect adjustment as of the beginning of the first year restated. The adoption of FIN 46 is not expected to have a material effect on the Company's financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No 5, 57 and 107 and recession of FASB Interpretation No. 34 (FIN 45). This interpretation clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. It also elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. The recognition and measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective

for financial statements of periods ending after December 15, 2002. The adoption of FIN 45 did not have a material effect on the Company's 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 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-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 in the Company's Form 8-K dated July 7, 2003 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; failure to acquire and develop new product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; limited patents and proprietary rights; dependence on market exclusivity; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; 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.

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 currently has six compounds in development: trospium for overactive bladder, paxlofen for panic and generalized anxiety disorders, citicoline for ischemic stroke, IP 751 for pain and inflammatory disorders, PRO 2000 for the prevention of infection by HIV and other sexually transmitted pathogens, and aminocandin for treatment of systemic fungal infections.

Major Products

Trospium is a muscarinic receptor antagonist in development as a treatment for overactive bladder. On April 28, 2003, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for trospium, and on June 30, 2003, the Company announced that the FDA accepted the NDA for review. The Company is evaluating commercial opportunities for the drug. In December 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. In March 2003, the Company signed an exclusive development agreement

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

with Shire under which Shire is developing extended release formulations of trospium. As part of its ongoing development program, the Company is conducting additional clinical trials in the U.S. to explore further certain attributes of trospium.

Pagoclone is a novel GABA (gamma amino butyric acid) receptor agonist in development for the treatment of anxiety disorders. Pagoclone is in Phase III testing for panic disorder and Phase II testing for generalized anxiety disorder. The Company is pursuing a new worldwide development and commercialization partnership for pagoclone.

Citicoline has been under development by the Company as a neuroprotective treatment for ischemic stroke. The Company continues to have discussions with the FDA regarding the design, clinical endpoints and number of additional clinical trials that may be necessary to complete development of citicoline sufficient for filing an NDA. The Company does not plan to develop citicoline further without a corporate partnership or project-specific funding.

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. A Phase I clinical trial designed to assess the safety of IP 751 showed that it was well tolerated, with no clinically significant adverse events and no evidence of psychotropic activity. An Investigative New Drug application (IND) for IP 751 has been filed with the FDA. The Company is currently scaling up manufacturing of IP 751 and plans to initiate clinical trials in 2004.

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 which began in June 2003. In addition, a 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 is responsible for supplying clinical materials for use in these trials. In April 2003, the Company amended the terms of the PRO 2000 licensing agreement with Paligent. Paligent agreed to relinquish a potential future \$500,000 milestone payment and provide Indevus an option to acquire all rights to PRO 2000 by a certain future date in exchange for an immediate payment and an optional buyout payment by Indevus.

Aminocandin is a member of a new class of anti-fungal compounds in development for the treatment of a broad spectrum of systemic, invasive infections. The Company licensed exclusive, worldwide rights to aminocandin from Aventis in April 2003. In exchange for these rights and for Aventis' inventory of aminocandin, Indevus made an up-front payment to Aventis and is obligated to pay potential milestones and royalties on future sales. The Company expects aminocandin will be ready for Phase I clinical testing during 2003. Under the Aventis Agreement, Indevus is responsible for all development and commercialization activities for both intravenous and oral formulations of aminocandin. Aventis has agreed to manufacture the key component of aminocandin, using its proprietary fermentation technology.

The Company licensed to Lilly exclusive, worldwide rights to Indevus' patent covering the use of fluoxetine to treat certain conditions and symptoms associated with premenstrual syndrome. The drug is being marketed by Lilly under the trade name Sarafem. In December 2002, the Company entered into a renegotiated 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 included 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 and reflected as royalty revenue. 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

We believe 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 judgments 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. 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.

Significant Judgments and Estimates

Insurance Claim Receivable

As of June 30, 2003, the Company had an outstanding insurance claim of approximately \$3,700,000, for services rendered through May 30, 2001 by the group of law firms defending the Company in the Redux-related product liability

litigation. 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 claim 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 approximately \$2,500,000 against the insurance claim on Reliance as of June 30, 2003 is a significant estimate reflecting management's judgment. 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 approximately \$1,200,000 for Redux-related expenses, including legal expenses. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at June 30, 2003. To the extent the amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

Results of Operations

Total revenues increased to \$714,000 in the three month period ended June 30, 2003 from \$228,000 in the three month period ended June 30, 2002 and increased to \$4,407,000 in the nine month period ended June 30, 2003 compared to \$3,855,000 in the nine month period ended June 30, 2002. Royalty revenue relates to royalties received from Lilly for sales of Sarafem. Royalty revenue increased \$476,000, or 211%, to \$702,000 in the three month period ended June 30, 2003 from \$226,000 in the three month period ended June 30, 2002. Royalty revenue in the fiscal 2002 three month period was recognized according to the Company's original agreement with Lilly which was in dispute between the two companies at that time and which minimized royalty revenue in that period. Royalty revenue for the nine month period ended June 30, 2003 was \$3,559,000 compared to \$3,439,000 for the nine month period ended June 30, 2002. The fiscal 2003 nine month period included \$2,184,000 of accelerated milestone payments received from Lilly in February 2003 pursuant to the Company's renegotiated agreement with Lilly (see Note E of Notes to Unaudited Consolidated Financial Statements) and the fiscal 2002 nine month period included \$3,199,000 of royalty revenue which resulted from sales of Sarafem in a higher royalty payment bracket pursuant to the Company's original agreement with Lilly. Contract and license fee revenue of \$848,000 in the nine month period ended June 30, 2003 consisted primarily of \$777,000 from an initial payment received from Lilly related to the renegotiated agreement for Sarafem. The balance of contract and license fee revenue relates to a research grant related to certain PRO 2000 development costs.

Cost of revenues in the three and nine month periods ended June 30, 2003 and 2002 consisted primarily of amounts due to MIT for their portion of the contractual payments and royalties received from Lilly. Additionally, cost of revenues includes the development costs related to the PRO 2000 research grant.

Research and development expenses increased \$4,508,000, or 107%, to \$8,718,000 in the three month period ended June 30, 2003 from \$4,210,000 in the three month period ended June 30, 2002 and increased \$5,778,000, or 58%, to \$15,735,000 in the nine month period ended June 30, 2003 from \$9,957,000 in the nine month period ended June 30, 2002. These increases are substantially related to tropsium and include increased clinical costs, including trial initiation costs for the ongoing clinical trial, development of extended release formulations of tropsium, and costs related to the preparation of the NDA. The three and nine month periods ended June 30, 2003 also include aggregate payments and license fees of \$2,000,000 related to aminocandin and PRO 2000, and the three and nine month periods ended June 30, 2002 include a license fee of \$500,000 related to IP 751. The increase in the nine month period ended June 30, 2003 was partially offset by a decrease of noncash expense related to a stock option grant and modifications of stock option grants to an executive officer of the Company in fiscal 2002. The Company expects to continue to incur significant costs in fiscal 2003 related to tropsium.

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Marketing, general and administrative expense increased \$2,252,000, or 131%, to \$3,976,000 in the three month period ended June 30, 2003 from \$1,724,000 in the three month period ended June 30, 2002 and increased \$2,686,000, or

45%, to \$8,593,000 in the nine month period ended June 30, 2003 from \$5,907,000 in the nine month period ended June 30, 2002. These increases are primarily due to pre-marketing activities for trospium, including costs related to the Company's attendance at the American Urological Association convention in April 2003. In connection with the filing and FDA acceptance of the NDA for trospium, the Company has increased its rate of expenditure for trospium pre-marketing activities. The increase in the nine month period ended June 30, 2003 was partially offset by a decrease of noncash expense related to modifications of stock option grants to directors and executive officers of the Company in fiscal 2002 and other stock option grants to consultants. The Company expects to incur increased trospium pre-marketing costs in fiscal 2003.

Investment income decreased \$135,000, or 58%, to \$99,000 in the three month period ended June 30, 2003 from \$234,000 in the three month period ended June 30, 2002 and decreased \$311,000, or 41%, to \$449,000 in the nine month period ended June 30, 2003 from \$760,000 in the nine month period ended June 30, 2002. These decreases resulted from reduced market interest rates on lower weighted average invested cash balances. As a result of the July 2003 issuance of \$72,000,000 of Notes (see Note F of Notes to Unaudited Consolidated Financial Statements), the Company will commence incurring interest expense at an annual rate of approximately \$5,200,000, which includes approximately \$700,000 of amortization of deferred offering costs, and expects investment income to increase.

Impairment of equity securities of \$487,000 in the three and nine month periods ended June 30, 2002 reflects the write down of the Company's investment in Incara, Inc. (Incara) to fair value as the decline in Incara common stock was deemed other than temporary.

For the three month period ended June 30, 2003, the Company had a net loss of \$(12,050,000), or \$(0.26) per share, basic and diluted, compared to a net loss of \$(6,015,000), or \$(0.13) per share, basic and diluted, for the three month period ended June 30, 2002. For the nine month period ended June 30, 2003, the Company had a net loss of \$(20,447,000), or \$(0.44) per share, basic and diluted, compared to a net loss of \$(12,769,000), or \$(0.28) per share, basic and diluted, for the nine month period ended June 30, 2002. These increased losses are primarily due to increased research and development and marketing, general and administrative expenses as described above.

The Company expects to report losses for its consolidated operations for fiscal 2003.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At June 30, 2003, the Company had consolidated cash, cash equivalents and marketable securities of \$24,487,000 compared to \$41,543,000 at September 30, 2002. This decrease of \$17,056,000 primarily represents cash used in operating activities.

In July 2003, the Company received net proceeds of approximately \$68,600,000 from the sale of \$72,000,000 aggregate principal amount of 6.25% Convertible Senior Notes due 2008 (the Notes) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. This sale included the exercise by the initial purchasers of an option to purchase an additional \$12,000,000 aggregate principal amount of the Notes. The Notes are convertible at anytime prior to the July 15, 2008 maturity date into the Company's Common Stock at an initial conversion price of \$6.656 per share, subject to adjustment for certain events; the Company has reserved approximately 10,800,000 shares of Common Stock for issuance pursuant to such a conversion and agreed to file a registration statement with the SEC for such shares. Additionally, all or a portion of the Notes are redeemable by the Company for cash at any time after July 20, 2006 provided our Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period and all of the Notes are subject to repurchase by the Company at the option of the Note holders if a change in control occurs. Interest is payable semiannually in arrears on January 15 and July 15 through the maturity date.

The Company is continuing to invest substantial amounts in the ongoing development and pre-commercialization activities related to trospium. The Company does not currently have sufficient funds to commercialize trospium and is currently in discussions with prospective partners for the commercialization of trospium. The Company believes it has sufficient cash for currently planned expenditures for the next twelve months.

The Company will require additional funds or corporate collaborations for the development and commercialization of its other 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. If additional funds are not obtained, the Company will be required to delay product development and business development activities.

Product Development

The Company expects to continue to expend substantial additional amounts for the development of its products. In particular, the Company is continuing to expend substantial funds for trospium, including clinical trials to explore further certain attributes of trospium and the development of extended release formulations. 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 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 has entered into an agreement with Madaus under which it anticipates Madaus will manufacture trospium for commercial use provided that it can deliver acceptable product to satisfy U.S. regulatory and market requirements. Although Madaus manufactures the product for sale in Europe, it has not yet been inspected for compliance with U.S. current Good Manufacturing Practice (cGMP) requirements. The Company is working with Madaus to prepare for an FDA inspection of their German manufacturing plant. In order to manufacture the product for sale in the United States, Madaus' manufacturing facility must comply with U.S. cGMP. Failure to meet U.S. cGMP requirements in a timely manner could cause a material delay in FDA approval, if any, and commercialization of trospium. While we 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 FDA approval, if any, and commercialization of trospium.

Total research and development expenses incurred by the Company through June 30, 2003 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: \$41,600,000 for trospium, \$17,200,000 for pagoclone, \$82,300,000 for citicoline, \$8,900,000 for PRO 2000, \$1,600,000 for aminocandin and \$700,000 for IP 751. In June 2002, the Company re-acquired rights to pagoclone from Pfizer Inc. 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 was 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 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 June 30, 2003 through the preparation of an NDA for its major compounds currently being developed as follows: approximately \$15,000,000 for PRO 2000, approximately \$45,000,000 for IP 751, approximately \$30,000,000 for aminocandin, and approximately \$40,000,000 for pagoclone. In addition, the Company is continuing to expend substantial funds for trospium. The Company does not plan to develop citicoline further without a corporate partner or project-specific funding. The Company cannot reasonably estimate the 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 nine month period ended June 30, 2003 of \$17,079,000 consisted primarily of the net loss of \$20,447,000 offset by an increase in accrued expenses and other liabilities of \$2,771,000.

Cash provided by investing activities during the nine month period ended June 30, 2003 of \$14,590,000 consisted primarily of \$14,605,000 of net inflows from maturities and sales of marketable securities.

Commitments and Contingencies

At June 30, 2003 the Company's future minimum payments under non-cancelable lease arrangements were as follows:

<u>Fiscal Year</u>	<u>Operating Leases</u>
2003	\$ 138,000
2004	560,000
2005	555,000
2006	568,000
2007	312,000
Thereafter	
	<hr/>
Total lease payments	\$ 2,133,000
	<hr/>

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.

As a result of the issuance of the Notes, the Company has annual interest payment obligations of \$4,500,000 payable semi-annually in January and July and commencing in January 2004.

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

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 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 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 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, 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 have been made in these interim financial statements. The Company does not intend to adopt the accounting provision of SFAS No. 123 in the fiscal year ending September 30, 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of ARB No. 51 (FIN 46). This interpretation addresses the consolidation of certain variable interest entities (VIE s) for which a controlling financial interest exists. FIN 46 applies immediately to financial interest obtained in VIEs after January 31, 2003. It applies in the first fiscal year or interim period beginning after June 15, 2003, to VIEs in which a financial interest was obtained before February 1, 2003. FIN 46 may be applied prospectively with a cumulative effect adjustment of by restating previously issued financial statements with a cumulative effect adjustment as of the beginning of the first year restated. The adoption of FIN 46 is not expected to have a material effect on the Company s financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No 5, 57 and 107 and recession of FASB Interpretation No. 34 (FIN 45). This interpretation clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. It also elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. The recognition and measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements of periods ending after December 15, 2002. The adoption of FIN 45 did not have a material effect on the Company s 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 and 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 as

of June 30, 2003.

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: On September 15, 1997, the Company announced a market withdrawal of its first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by Wyeth, our licensee, in June 1996. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. These observations, presented to Indevus in September 1997, indicated an incidence of abnormal echocardiogram findings in approximately 30% of such patients. Although these observations reflected a preliminary analysis of pooled information and were difficult to evaluate because of the absence of matched controls and pretreatment baseline data for these patients, Indevus believed it was prudent, in light of this information, to withdraw Redux from the market.

Since the withdrawal of Redux, the Company has been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, some of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. To date, there have been no judgments against Indevus, nor has it paid any amounts in settlement of any of these claims. 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.

On May 30, 2001, the Company entered into an indemnity and release agreement with Wyeth, formerly American Home Products Corporation, pursuant to which Wyeth has agreed to indemnify Indevus against certain classes of product liability cases filed against the Company related to

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Redux. Indevus' 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 certain additional insurance coverage to supplement the Company's existing product liability insurance. Indevus 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 indemnity and release agreement will not have a material adverse

effect on our 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 indemnity and release agreement, the Company's defense costs were paid by, or subject to reimbursement to it from, its product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by Indevus or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to the Company by Wyeth, Indevus 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.

Pursuant to agreements between the parties, under certain circumstances, the Company may be required to indemnify Les Laboratoires Servier, Boehringer Ingelheim Pharmaceuticals, Inc. and other parties.

General: 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.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- 4.1 Indenture, between the Company and The Bank of New York, as Trustee, dated July 16, 2003
- 4.2 Resale Registration Rights Agreement between the Company and the Initial Purchasers of the Notes, dated July 16, 2003
- 10.132 License Agreement by and between Aventis Pharma SA and Indevus Pharmaceuticals, Inc. effective as of April 18, 2003 (1)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 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
- 32.2 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

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

(b) Reports on Form 8-K

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

On May 19, 2003, the Company filed a current report on Form 8-K reporting that on May 13, 2003, the Company issued a press release announcing its second quarter fiscal 2003 results.

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: August 13, 2003

By:

/s/ Glenn L. Cooper

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

(Principal Executive Officer)

Date: August 13, 2003

By: /s/ Michael W. Rogers

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

(Principal Financial Officer)

Date: August 13, 2003

By: /s/ Dale Ritter

Dale Ritter, Senior Vice President, Finance

(Principal Accounting Officer)