INDEVUS PHARMACEUTICALS INC
Form 10-Q
February 13, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 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	**04-3047911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

One Ledgemont Center **99 Hayden Avenue** **Lexington, Massachusetts**	**02421-7966**
(Address of principal executive offices)	**(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 x No ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12(b)-2 of the Exchange Act.) Yes x No ¨

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

Class:	**Outstanding at February 11, 2004**
Common Stock $.001 par value	**47,270,244 shares**

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Item 1. Financial Statements

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(Amounts in thousands except share data)

	December 31, 2003	September 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,698	$ 57,717
Marketable securities	26,881	26,370
Accounts receivable	208	155
Prepaids and other current assets	1,855	1,241
Total current assets	75,642	85,483
Equity securities	112	134
Property and equipment, net	32	33
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	2,998	3,163
Total assets	$ 80,042	$ 90,071
LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,291	$ 1,958
Accrued expenses	9,931	8,721
Accrued interest	2,062	938
Total current liabilities	13,284	11,617
Convertible Notes	72,000	72,000
License fees payable	200	200
Minority interest	9	13
STOCKHOLDERS DEFICIT		
Preferred stock, $.001 par value, 5,000,000 shares authorized;		
Series B, 239,425 shares issued and outstanding (liquidation preference at December 31, 2003 $3,034);	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at December 31, 2003 $503)	500	500
Common stock, $.001 par value, 80,000,000 shares authorized; 47,270,244 and 47,175,661 shares issued and outstanding at December 31 and September 30, 2003, respectively	47	47
Additional paid-in capital	303,814	303,452
Accumulated deficit	(312,715)	(300,691)

Accumulated other comprehensive loss	(97)	(67)
Total stockholders equity (deficit)	(5,451)	6,241
Total liabilities and stockholders equity (deficit)	$ 80,042	$ 90,071

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, 2003 and 2002

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended December 31,	
	2003	**2002**
Revenues:		
Royalties	$ 785	$
Contract and license fees	142	822
Total revenues	927	822
Costs and expenses:		
Cost of revenues	315	210
Research and development	7,554	3,777
Marketing, general and administrative	4,016	2,457
Total costs and expenses	11,885	6,444
Loss from operations	(10,958)	(5,622)
Investment income	222	191
Interest expense	(1,292)	
Minority interest	4	
Net loss	$ (12,024)	$ (5,431)
Net loss per common share:		
Basic and diluted	$ (0.25)	$ (0.12)
Weighted average common shares outstanding:		
Basic and diluted	47,211	46,876

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, 2003 and 2002

(Unaudited)

(Amounts in thousands)

	Three months ended December 31,	
	2003	**2002**
Cash flows from operating activities:		
Net loss	$ (12,024)	$ (5,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6	4
Amortization of convertible note issuance cost	165	
Minority interest in net income of consolidated subsidiary	(4)	
Change in assets and liabilities:		
Accounts receivable	(53)	487
Prepaid and other assets	(614)	(458)
Accounts payable	(667)	463
Accrued expenses and other liabilities	2,324	(501)
Net cash used in operating activities	(10,867)	(5,436)
Cash flows from investing activities:		
Capital expenditures	(5)	(10)
Purchase of marketable securities	(3,210)	(2,689)
Proceeds from maturities and sales of marketable securities	2,692	4,382
Net cash provided by (used in) investing activities	(523)	1,683
Cash flows from financing activities:		
Net proceeds from issuance of common stock	371	
Net cash provided by financing activities	371	
Net change in cash and cash equivalents	(11,019)	(3,753)
Cash and cash equivalents at beginning of period	57,717	19,977
Cash and cash equivalents at end of period	$ 46,698	$ 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, 2003.

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, 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) the notes convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 3,206,000 shares of Common Stock at prices ranging from $5.72 to $20.13 with expiration dates ranging up to May 13, 2012 and (iii) warrants to purchase 55,000 shares of Common Stock with exercise prices ranging from $5.00 to $6.19 and with expiration dates ranging up to July 17, 2006. Additionally, during the three month period ended December 31, 2003, potentially dilutive 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 6,985,000 shares of Common Stock at prices ranging from $1.22 to $5.32 with expiration dates ranging up to June 3, 2013 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

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 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; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

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 December 31,	
	2003	**2002**
As reported net loss	$ (12,024,000)	$ (5,431,000)
Adjustment to compensation expense for stock-based awards	$ (302,000)	$ (274,000)
Pro forma net loss	$ (12,326,000)	$ (5,705,000)
As reported net loss per common share, basic and diluted	$ (0.25)	$ (0.12)
Pro forma net loss per common share, basic and diluted	$ (0.26)	$ (0.12)

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D. *Comprehensive Loss*

Comprehensive loss for the three month periods ended December 31, 2003 and 2002, respectively, is as follows:

	Three Months Ended December 31,	
	2003	2002
Net loss	$ (12,024,000)	$ (5,431,000)
Change in unrealized net gain or loss on investments	(30,000)	(6,000)
Comprehensive loss	$ (12,054,000	$ (5,437,000)

E. *Agreements*

In October 2003, CPEC LLC, a consolidated subsidiary, licensed its bucindolol development and marketing rights to ARCA Discovery, Inc. in exchange for potential future milestone and royalty payments.

Effective January 22, 2004, we entered into a new agreement with Ferrer Internacional S.A. (Ferrer) covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, we have granted Ferrer exclusive rights to our patents and know-how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing, and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product.

F. *Recent Accounting Pronouncement*

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, (FIN 46). FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity (VIE), the assets, liabilities and results of activities of the VIE should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. The Company does not have any financial interests in VIE s created after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 requires its provisions, as amended by FIN 46R which was issued by the FASB in December 2003, be adopted by the Company in the second quarter of fiscal 2004. The adoption of FIN 46R is not expected to have a material impact 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 us 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: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including trospium; our 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 10-K for its fiscal year ended September 30, 2003. 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 our products, including trospium; risks associated with contractual agreements; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners, including the commercialization of trospium and the development of our other product candidates; failure to acquire and develop additional 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 our 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, 2003. Unless the context indicates otherwise, Indevus, the Company, we or us refer to Indevus Pharmaceuticals, Inc.

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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. We currently have rights to six compounds in development: trospium for overactive bladder, pagoclone 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.

Recent Product Developments

Trospium

We submitted the New Drug Application (NDA) for trospium for overactive bladder (OAB) on April 28, 2003. Pursuant to the NDA, the trospium finished product will be manufactured by our licensor, Madaus AG, at their manufacturing facility in Germany. The U.S. Food and Drug Administration (FDA) conducted a pre-approval inspection at this site in early February 2004. No significant issues were noted by the inspector, and therefore, we are now initiating a manufacturing campaign to have launch quantities of finished product available by June or July, 2004.

FDA requires drugs in the pharmacological class to which trospium belongs (muscarinic receptor antagonists), and most new drugs, to undergo rigorous analysis to determine if they have any clinically significant effect on the QT interval of cardiac muscle contractility. Administration of drugs that significantly prolong the QT interval may lead to serious or fatal cardiac arrhythmias. The NDA for trospium contained a placebo-controlled study conducted by the sponsor to assess the effect of trospium on the QT interval. The study was designed with FDA input and was considered the current standard at that time. The study concluded that trospium administration did not prolong the QT interval. In November 2002, the FDA issued a preliminary concept paper concerning the clinical evaluation of QT interval prolongation for non-antiarrhythmia drugs which stipulated that QT interval studies should have larger sample sizes than previously required, should include a greater number of ECG readings than previously required, and should include a positive control, such as the drug moxifloxacin, which causes a predictable increase in the QT interval. In late 2003, we became aware that a competitive overactive bladder product with a pending NDA received an approvable letter, requiring the sponsor to perform a QT study. A second competitive OAB product also received an approvable letter with a requirement to perform additional unspecified clinical studies. Although we believe that our QT study of trospium, completed in 2001, demonstrated no effect on the QT interval, we decided to perform a second QT study with the new standard as described in the November 2002 FDA concept paper. FDA was consulted on the study design, the study was completed in late 2003, and the final study report was recently submitted to FDA. The study demonstrated that both trospium and placebo had no significant effect on the QT interval while moxifloxacin, the positive comparator, had an expected increase in QT interval. Thus, the study concluded that trospium has no significant effect on the QT interval.

As a result of the submission of this new QT study, we received a letter dated February 12, 2004, from the FDA establishing a 90-day extension to the original Prescription Drug User Fee Act (PDUFA) action date of February 27, 2004, moving that date to May 28, 2004.

We have also recently completed a successful trial designed to explore further certain attributes of trospium. The 12-week, placebo-controlled trial enrolled 658 patients at 52 sites in the U.S. Preliminary results show that the trial met all of its primary and secondary endpoints with a high degree of statistical significance, including a reduction in both micturitions (urinations) and urinary incontinence episodes among patients treated with trospium versus placebo. In particular, the study confirmed a rapid onset of action within one week of therapy and a significant reduction in

urge severity. The most frequent side effects seen in the trial were the common anti-cholinergic side effects of dry mouth and constipation, with results consistent with our previous studies. We hope to use these findings in discussions with the FDA to support proposed statements in the product label which may help reinforce trospium s position in the marketplace. We also intend to submit the results of the study for presentation in scientific forums and publication in peer-reviewed journals.

We intend to enter into a commercialization agreement for the launch and marketing of trospium. We have entered into late stage negotiations for a trospium marketing partnership that, if consummated, would allow us to establish a specialty sales force and co-promote trospium. As part of our continuing development program, we are also conducting additional clinical trials in the U.S. to develop extended release formulations of trospium.

Citicoline

Effective January 22, 2004, we entered into a new agreement with Ferrer Internacional S.A. (Ferrer) covering the development, manufacture, and marketing of citicoline in the U.S. and Canada. Under the terms of the new agreement, we have granted Ferrer exclusive rights to our patents and know-how related to citicoline. In exchange, Ferrer agreed to assume all future development, manufacturing, and commercialization costs of citicoline. Indevus will receive 50% of all milestone payments made to Ferrer by a third party and royalties on net sales of the product. This new agreement allows Indevus to retain significant participation in the future economics of citicoline, should the product be approved and marketed in the U.S. and Canada, without incurring any further costs.

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 our 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, 2003, we consider our revenue recognition policy critical and therefore we state it below.

Revenue Recognition

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and is recognized when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance

with the related license agreement.

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of our 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 we have 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 we have no further performance obligations under the license agreement. In multiple-element revenue arrangements, if the license does not have stand alone value or if the Company does not have objective and reliable evidence of the fair value of the undelivered products or services, the amount of revenue allocable to the license is deferred and recognized over the performance period of the arrangement or when the Company s performance under the arrangement is complete.

Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which we

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have 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. Determination as to whether a milestone meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations or when the Company s performance under the arrangement is complete.

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

Significant Judgments and Estimates

Insurance Claim Receivable

As of December 31, 2003, we had an outstanding insurance claim of approximately $3,700,000, for services rendered through May 30, 2001 by the group of law firms defending us in the Redux-related product liability litigation. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company (Reliance), which is in liquidation proceedings. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we have recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $1,258,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately $2,400,000 against the insurance claim on Reliance as of December 31, 2003 is a significant estimate reflecting management s judgment. To the extent we do not collect the insurance claim receivable of $1,258,000, we would be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

Results of Operations

Our net loss increased $6,593,000 to $(12,024,000), or $(0.25) per share, basic, in the first quarter of fiscal 2004 from $(5,431,000), or $(0.12) per share, basic, in the first quarter of fiscal 2003. This increased net loss is primarily the result of our continuing development and pre-marketing activities related to trospium.

Total revenues increased $105,000, or 13%, to $927,000 in the three month period ended December 31, 2003 from $822,000 in the three month period ended December 31, 2002. Royalty revenue of $785,000 in the three month period ended December 31, 2003 relates to royalties received from Eli Lilly & Company (Lilly) for sales of Sarafem. 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 renegotiated agreement for Sarafem. Contract and license fee revenue of $142,000 in the first quarter of fiscal 2004 relates to a research grant related to certain PRO 2000 development costs.

Cost of revenues in the three month periods ended December 31, 2003 and 2002 consisted primarily of amounts due to Massachusetts Institute of Technology for their portion of the royalties and contractual payments received from Lilly. Additionally, cost of revenues includes the development costs related to the PRO 2000 research grant.

Research and development expenses increased $3,777,000, or 100%, to $7,554,000 in the three month period ended December 31, 2003 from $3,777,000 in the three month period ended December 31, 2002. This increase is primarily related to trospium. Trospium-related research and development expenses in the three month period ended December 31, 2003 include clinical trial costs, costs related to the development of extended release formulations of trospium and other development costs.

Marketing, general and administrative expense increased $1,559,000, or 63%, to $4,016,000 in the three month period ended December 31, 2003 from $2,457,000 in the three month period ended December 31, 2002. This increase is primarily due to increased pre-marketing activities related to trospium.

Investment income increased $31,000, or 16%, to $222,000 in the three month period ended December 31, 2003 from $191,000 in the three month period ended December 31, 2002. While average invested balances have increased, market rates have substantially decreased from 2002 resulting in a modest increase in investment income in the three month period ended December 31, 2003 compared to the three month period ended December 31, 2002.

Interest expense of $1,292,000 in the three month period ended December 31, 2003 results from our July 2003 issuance of $72,000,000 of 6.25% Convertible Senior Notes due 2008 (the Notes). Annual interest expense is expected to be approximately $5,200,000, which includes approximately $700,000 of amortization of debt issuance costs.

The Company expects to report losses for its consolidated operations for fiscal 2004.

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Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At December 31, 2003, we had consolidated cash, cash equivalents and marketable securities of $73,579,000 compared to $84,087,000 at September 30, 2003. This decrease of $10,508,000 resulted primarily from $10,867,000 of cash used by operating activities.

We are continuing to invest substantial amounts in the ongoing development and pre-commercialization activities related to trospium. We do not currently have sufficient funds to commercialize trospium and are currently in discussions with prospective partners for the commercialization of trospium. We believe we have sufficient cash for currently planned expenditures for the next twelve months.

We will require additional funds or corporate collaborations for the development and commercialization of our other compounds in development, as well as any new businesses, products or technologies acquired or developed in the future. We have no commitments to obtain such funds. There can be no assurance that we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If additional funds are not obtained, we may be required to delay product development and business development activities.

Product Development

We expect to continue to expend substantial additional amounts for the development of our products. In particular, we are 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 we will have sufficient funds to develop or commercialize any of our products.

We have entered into an agreement with Madaus under which we anticipate Madaus will manufacture trospium for commercial use provided that it can deliver acceptable product to satisfy U.S. regulatory and market requirements. In order to manufacture the product for sale in the United States, Madaus manufacturing facility must comply with cGMP. Failure to meet 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 us through December 31, 2003 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: $56,800,000 for trospium, $18,300,000 for pagoclone, $82,400,000 for citicoline, $9,700,000 for PRO 2000, $1,800,000 for aminocandin and $2,200,000 for IP 751. In June 2002, we 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 our development costs. In the event we 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 us 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, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from December 31, 2003 through the preparation of an NDA for our 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 $38,000,000 for pagoclone. Pursuant to our new agreement with Ferrer regarding citicoline, Ferrer is responsible for all future costs for the development of citicoline. We 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. We are unable to estimate the date

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of development completion for citicoline because Ferrer is now responsible for its development. We are unable to estimate the date of development completion for pagoclone due to the scope complexity and cost of the type of clinical trials necessary which may require the financial assistance of a partner to complete. Actual costs and time to complete any of our products may differ significantly from the estimates.

Analysis of Cash Flows

Cash used in operating activities for the three month period ended December 31, 2003 of $10,867,000 consisted primarily of the net loss of $12,024,000 offset by a net increase in accounts payable and accrued expenses and other liabilities of $1,657,000. Accrued expenses and other liabilities increased $2,324,000 in the three month period ended December 31, 2003 primarily due to increased trospium development and pre-marketing activities.

In January 2004, we paid $2,237,500 of interest due on our Notes and will pay a similar amount in July 2004. Additionally, during the quarter ending March 31, 2004, we expect certain accrued expenses will be reduced through payments.

Commitments

In February 2004, we issued a purchase order to Madaus, pursuant to the supply agreement between our two companies, to purchase from Madaus manufactured trospium tablets in bulk form to be used for a potential launch of the product. The current value of this purchase order is approximately $8,000,000, based upon current exchange rates. If trospium is approved for marketing by the FDA and we launch trospium in the United States, we will be committed to purchase from Madaus significant additional quantities of manufactured trospium tablets in bulk form during the initial launch year.

Other

Recent Accounting Pronouncement

In January 2003, the FASB issued FIN 46. FIN 46 requires that if an entity has a controlling financial interest in a VIE, the assets, liabilities and results of activities of the VIE should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. We do not have any financial interests in VIE s created after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 requires its provisions, as amended by FIN 46R which was issued by the FASB in December 2003, be adopted by us in the second quarter of fiscal 2004. The adoption of FIN 46R is not expected to have a material impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Interest Rate Risk related to Cash, Cash Equivalents and Marketable Securities

We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars and are subject to interest rate risk, and could decline in value if interest rates fluctuate. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and we have implemented guidelines limiting the duration of investments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

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Risk related to the Notes

The fair value of our Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a $1000 Note by approximately $63. An increase in market interest rates could result in a decrease in the fair value of the Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a $1000 Note by approximately $20. The two examples provided above are only hypothetical and actual changes in the value of the Notes due to fluctuations in market value of our Common Stock or interest rates could vary substantially from these examples.

Item 4. Controls and Procedures

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 as of December 31, 2003. 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 was no significant change in our internal controls during the fiscal quarter ended December 31, 2003 that has materially affected or is reasonably likely to materially affect those controls.

PART II. Other Information

Item 1. Legal Proceedings

Product Liability Litigation. On September 15, 1997, we announced a market withdrawal of our 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 us 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, we believed it was prudent, in light of this information, to withdraw Redux from the market.

Since the withdrawal of Redux, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. To date, there have been no judgments against us, nor have we 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, we entered into an indemnity and release agreement with Wyeth, formerly American Home Products Corporation, pursuant to which Wyeth has agreed to indemnify us against certain classes of product liability cases filed against us related to Redux. Our indemnification covers plaintiffs who initially 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 our defense of Redux-related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance

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coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our 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 we are not otherwise indemnified or covered under the AHP 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 our ability to obtain sufficient financing to fund operations. Up to the date of the AHP indemnity and release agreement, our defense costs were paid by, or subject to reimbursement to us from, our product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by us or our insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to us by Wyeth, we agreed to dismiss our suit against Wyeth filed in January 2000, our appeal from the order approving Wyeth s national class action settlement of diet drug claims and our cross-claims against Wyeth related to Redux product liability legal actions.

Pursuant to agreements we have with Les Laboratoires Servier, from whom we in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities.

General. Although we maintain certain product liability and director and officer liability insurance and intend to defend these and similar actions vigorously, we have 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 us and our officers and directors, our 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 our common stock and on our 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 us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

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

(b) Reports on Form 8-K

On December 19, 2003, the Company filed a current report on Form 8-K reporting that on December 18, 2003, the Company issued a press release announcing its fiscal 2003 results.

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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 12, 2004 By: /s/ GLENN L. COOPER

Glenn L. Cooper, M.D., Chairman, President,

and Chief Executive Officer

(Principal Executive Officer)

Date: February 12, 2004 By: /s/ MICHAEL W. ROGERS

Michael W. Rogers, Executive Vice President,

Chief Financial Officer and Treasurer

(Principal Financial Officer)

Date: February 12, 2004 By: /s/ DALE RITTER

Dale Ritter, Senior Vice President, Finance

(Principal Accounting Officer)