INDEVUS PHARMACEUTICALS INC
Form 10-Q
August 16, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2004, 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	**02421-7966**

99 Hayden Avenue

Lexington, Massachusetts
(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 August 13, 2004
Common Stock $.001 par value	**46,663,696 shares**

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Item 1. Financial Statements

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(Amounts in thousands except share data)

	June 30, 2004	September 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 158,644	$ 57,717
Marketable securities	30,441	26,370
Accounts receivable	930	155
Prepaids and other current assets	4,899	1,241
Total current assets	194,914	85,483
Marketable securities	3,482	
Equity securities	112	134
Property and equipment, net	526	33
Insurance claim receivable	1,258	1,258
Prepaid debt offering costs	2,668	3,163
Other asset	2,000	
Total assets	$ 204,960	$ 90,071
LIABILITIES		
Current liabilities:		
Accounts payable	$ 2,215	$ 1,958
Accrued expenses	13,869	8,721
Accrued interest	2,075	938
Deferred revenue	12,641	
Total current liabilities	30,800	11,617
Convertible notes	72,000	72,000
License fees payable	150	200
Deferred revenue	135,889	
Minority interest	8	13
STOCKHOLDERS EQUITY (DEFICIT)		
Preferred stock, $.001 par value, 5,000,000 shares authorized;		
Series B, 239,425 shares issued and outstanding (liquidation preference at June 30, 2004 $3,019);	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at June 30, 2004 $500)	500	500
Common stock, $.001 par value, 80,000,000 shares authorized; 47,825,896 shares issued and outstanding at June 30, 2004 and 47,175,661 at September 30, 2003	48	47
Additional paid-in capital	305,407	303,452
Accumulated deficit	(342,703)	(300,691)

Accumulated other comprehensive loss	(139)	(67)
Total stockholders equity (deficit)	(33,887)	6,241
Total liabilities and stockholders equity (deficit)	$ 204,960	$ 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 and nine months ended June 30, 2004 and 2003

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended June 30,		Nine months ended June 30,	
	2004	2003	2004	2003
Revenues:				
Contract and license fees	$ 2,327	$ 12	$ 2,491	$ 848
Royalties	479	702	2,118	3,559
Total revenues	2,806	714	4,609	4,407
Costs and expenses:				
Royalty expense	98	157	459	904
Research and development	5,777	8,730	18,636	15,806
Marketing, general and administrative	14,572	3,976	24,370	8,593
Total costs and expenses	20,447	12,863	43,465	25,303
Loss from operations	(17,641)	(12,149)	(38,856)	(20,896)
Investment income	315	99	717	449
Interest expense	(1,293)		(3,878)	
Minority interest	1		5	
Net loss	$ (18,618)	$ (12,050)	$ (42,012)	$ (20,447)
Net loss per common share:				
Basic and diluted	$ (0.39)	$ (0.26)	$ (0.89)	$ (0.44)
Weighted average common shares outstanding:				
Basic and diluted	47,729	46,890	47,445	46,882

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 nine months ended June 30, 2004 and 2003

(Unaudited)

(Amounts in thousands)

	For the nine months ended June 30,	
	2004	**2003**
Cash provided by (used in) operating activities:		
Net loss	$ (42,012)	$ (20,447)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	52	12
Amortization of convertible notes issuance costs	495	
Minority interest in net income of consolidated subsidiary	(5)	
Change in assets and liabilities:		
Accounts receivable	(775)	476
Prepaid and other assets	(5,658)	(734)
Accounts payable	257	843
Deferred revenue	148,530	
Accrued expenses and other liabilities	6,244	2,771
Net cash provided by (used in) operating activities	107,128	(17,079)
Cash flows from investing activities:		
Capital expenditures	(545)	(15)
Purchases of marketable securities	(31,927)	(3,877)
Proceeds from maturities and sales of marketable securities	24,324	18,482
Net cash provided by (used in) investing activities	(8,148)	14,590
Cash flows from financing activities:		
Net proceeds from issuance of common stock	1,947	66
Net cash provided by financing activities	1,947	66
Net change in cash and cash equivalents	100,927	(2,423)
Cash and cash equivalents at beginning of period	57,717	19,977
Cash and cash equivalents at end of period	$ 158,644	$ 17,554

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 interim 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 in the United States of America 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.

For an entity that is not a variable interest entity under FIN 46, *Consolidation of Variable Interest Entities*, the Company s policy is to consolidate a subsidiary when the Company owns greater than 50% of the voting interest in the subsidiary and/or controls it.

Certain prior year amounts have been reclassified to conform to fiscal 2004 classifications.

Indevus is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including SANCTURA (trospium chloride), approved by the U.S. Food and Drug Administration for the treatment of overactive bladder, and multiple compounds in clinical development.

B. *Revenue Recognition Policy*

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company s licensed technologies and are generally reported to the Company in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based unless the royalty report for such period is received subsequent to the time the Company is required to report its results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, in which case the Company recognizes such royalty revenue in the subsequent accounting period when it receives the royalty report and 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.

Contract and license fee revenue is primarily generated through collaborative license and development or co-promotion agreements with strategic partners for the development and commercialization of the Company s products or 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. In multiple element arrangements where the Company has continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement.

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. 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 the Company completes its performance obligations.

Pursuant to Emerging Issues Task Force (EITF) 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products) all payments made to a customer (including a licensee of the Company s technology) are recorded as a reduction of revenue unless the Company receives an identifiable benefit in exchange for the payment that is sufficiently separable from the customer s agreement to license technology or purchase services from the Company and the Company can reasonably estimate the fair value of the benefit received. In accordance with EITF 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent reimbursement of costs, including advertising and promotion costs, by a licensee of the Company s technology are recorded as revenues when the Company is the primary obligor for the costs being reimbursed and bears the risk of credit loss.

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

C. *Basic and Diluted Loss per Common Share*

During the three month period ended June 30, 2004, 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 and (ii) options to purchase 501,000 shares of Common Stock at prices ranging from $7.37 to $20.13 with expiration dates ranging up to June 8, 2014. Additionally, during the three month period ended June 30, 2004, 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 9,629,000 shares of Common Stock at prices ranging from $1.22 to $7.10 with expiration dates ranging up to May 18, 2014; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock 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.

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 nine month period ended June 30, 2004, 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; and (ii) options to purchase 569,000 shares of Common Stock at prices ranging from $6.68 to $20.13 with expiration dates ranging up to June 8, 2014. Additionally, during the nine month period ended June 30, 2004, 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 9,548,000 shares of Common Stock at prices ranging from $1.22 to $6.25 with expiration dates ranging up to March 10, 2014; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock 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.

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 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.

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 or conversion of such securities.

D. *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 employee 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 employee 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,	
	2004	2003	2004	2003
As reported net loss	$ (18,618,000)	$ (12,050,000)	$ (42,012,000)	$ (20,447,000)
Adjustment to compensation expense for stock-based awards	$ (940,000)	$ (241,000)	$ (1,547,000)	$ (760,000)
Pro forma net loss	$ (19,558,000)	$ (12,291,000)	$ (43,559,000)	$ (21,207,000)
As reported net loss per common share, basic and diluted	$ (0.39)	$ (0.26)	$ (0.89)	$ (0.44)
Pro forma net loss per common share, basic and diluted	$ (0.41)	$ (0.26)	$ (0.92)	$ (0.45)

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E. *Comprehensive Loss*

Comprehensive loss for the three and nine month periods ended June 30, 2004 and 2003, respectively, is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2004	2003	2004	2003
Net loss	$ (18,618,000)	$ (12,050,000)	$ (42,012,000)	$ (20,447,000)
Change in unrealized net gain or (loss) on investments	(112,000)	30,000	(72,000)	(2,000)
Comprehensive loss	$ (18,730,000)	$ (12,020,000)	$ (42,084,000)	$ (20,449,000)

F. *Agreements*

SANCTURA:

Effective April 6, 2004, the Company entered into a co-promotion and licensing agreement with Odyssey Pharmaceuticals, Inc., a specialty branded subsidiary of Pliva d.d. (Pliva) (the Pliva Agreement) for the U.S. commercialization of SANCTURA (trospium chloride), approved for marketing on May 28, 2004 by the U.S. Food and Drug Administration (FDA) as a treatment for overactive bladder. The Company granted Pliva an exclusive right and license to co-promote and sell SANCTURA in the United States. The Pliva Agreement provides for payments to Indevus from Pliva that include $30 million received upon signing and $120 million received upon FDA approval of SANCTURA twice daily. In addition, Indevus could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of a once-a-day formulation of SANCTURA, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013.

For at least six months following the approval of SANCTURA, Indevus will receive a commission based on net sales of SANCTURA, adjusted by a fixed percentage of the aggregate advertising and promotion costs incurred by Pliva and Indevus. During this period, Indevus will be responsible for funding its own sales force and certain advertising and promotional costs. Pliva and Indevus will co-promote SANCTURA through a joint sales force of approximately 500 sales representatives. Indevus will establish a sales force initially numbering approximately 280 representatives who will promote SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

At any time beginning six months after the approval of SANCTURA, each company has the right to convert the Pliva Agreement into a royalty-bearing structure, whereby Indevus will receive royalties from Pliva based on net sales of SANCTURA, and Pliva will be responsible for promotional and advertising costs. Should this right be exercised, Indevus specialty sales force will be subsidized by Pliva for a specified period and will continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and high prescribers.

Under the Pliva Agreement, Indevus will be responsible for funding the development of the once-a-day formulation of SANCTURA. The Company is responsible for the manufacture and supply of SANCTURA and will sell it to Pliva at cost. Pliva will be responsible for product inventory management and sales order fulfillment including billing and collecting of customer receivables. The Pliva Agreement is subject to termination by Pliva under certain circumstances. Under the Pliva Agreement, Indevus granted a security interest to Pliva in Indevus rights relating to FDA rights in SANCTURA and agreed to indemnify Pliva under certain circumstances.

The Company recorded the $150,000,000 received from Pliva as deferred revenue. During the three and nine months ended June 30, 2004, the Company recognized as contract and license fee revenue $1,470,000 from amortization of the deferred revenue and $851,000 net reimbursement due to the Company comprised of Pliva s share of SANCTURA promotion and advertising costs incurred by Indevus less an amount owed by the Company to Pliva for Indevus share of SANCTURA promotion and advertising costs incurred by Pliva.

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Citicoline:

Effective January 22, 2004, the Company 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, the Company has granted Ferrer exclusive rights to its 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.

Bucindolol:

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.

PRO 2000:

Pursuant to research grants supporting certain PRO 2000 development costs, the Company reflected $6,000 and $170,000 of contract and license fee revenue in the three and nine month periods ended June 30, 2004, respectively, and $12,000 and $71,000 of contract and license fee revenue in the three and nine month periods ended June 30, 2003, respectively.

G. *Subsequent Event*

On July 1, 2004, the Company announced that its board of directors has authorized the repurchase from time to time of up to 2,500,000 shares of its common stock in open market transactions. Through August 13, 2004, the Company has repurchased 1,166,000 shares at an average price of approximately $6.24 per share.

H. *Recent Accounting Pronouncements*

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 Company s

adoption of FIN 46R in the second quarter of fiscal 2004 did not have a material impact on the Company s financial position or results of operations.

Emerging issues Task Force (EITF) 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share* (EITF 03-6), was issued in March 2004. EITF 03-6 is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. ETIF 03-6 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on the Company s consolidated financial position, results of operations or cash flows due to the net loss reported. In the event the Company reports net income, the Company will allocate undistributed earnings and report earnings per share accordingly.

I. *Withdrawal of Redux, Legal Proceedings, Insurance Claims, and Related Contingencies*

In May 2001, the Company entered into the AHP Indemnity and Release Agreement with Wyeth pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine), a prescription anti-obesity compound withdrawn from the market in September 1997. This 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 the Company s defense of Redux-related product liability cases. Also, pursuant to the agreement, Wyeth has funded additional insurance coverage to supplement the Company s existing product liability insurance. The Company believes this total insurance coverage is sufficient to address its potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which the Company is not otherwise indemnified or covered under the AHP Indemnity and Release Agreement will not have a material adverse effect on the Company s future business, results of operations or financial condition or that the potential of any such claims would not adversely affect the Company s ability to obtain sufficient

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financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the Company s defense costs were paid by, or subject to reimbursement to the Company from, the Company s product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers.

As of June 30, 2004, the Company had an outstanding insurance claim of $3,700,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company s current outstanding insurance claim is made pursuant to the Company s product liability policy issued to the Company by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company previously 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 amount the Company collects could differ from the $1,258,000 reflected as a noncurrent insurance claim receivable at June 30, 2004 and September 30, 2003. It is uncertain when, if ever, the Company will collect any of its $3,700,000 of estimated claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

At June 30, 2004, we have an accrued liability of approximately $700,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ from this amount. To the extent amounts paid differ from the amounts accrued, we will record a charge or credit to the statement 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 SANCTURA; 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 Post-Effective Amendment No. 4 to Registration Statement on Form S-3 as filed with the SEC on July 12, 2004. These factors include, but are not limited to: dependence on the success of SANCTURA; the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA; risks associated with contractual agreements, particularly for the manufacturing and co-promotion of SANCTURA; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners, including for the development of our products; 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.

Description of the Company

Indevus is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including SANCTURA (trospium chloride), approved by the FDA for the treatment of overactive bladder, and multiple other compounds in clinical development. We currently have rights to five compounds approved or in development: SANCTURA, pagoclone for panic and generalized anxiety disorders, 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.

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Recent Product Developments

SANCTURA

On May 28, 2004, our New Drug Application (NDA) for SANCTURA was approved by the FDA for the treatment of overactive bladder.

Effective April 6, 2004, the Company entered into the Pliva Agreement for the U.S. commercialization of SANCTURA, a treatment for overactive bladder. The Company granted Pliva an exclusive right and license to co-promote and sell SANCTURA in the United States. The Pliva Agreement provides for payments to Indevus from Pliva, including $150 million received during the quarter ended June 30, 2004, $30 million upon signing and $120 million upon FDA approval of SANCTURA twice daily. In addition, Indevus could receive up to $45 million in future payments contingent upon the achievement of certain milestones related to the development of a once-a-day formulation of SANCTURA, as well as a payment of $20 million related to the achievement of a long-term commercialization milestone in 2013. We initially recorded the $150 million received from Pliva during the quarter ended June 30, 2004 as deferred revenue which we are amortizing into contract and license fees on a straight-line basis over a currently-estimated 12 year duration of the Pliva Agreement. New information in future periods that could affect the duration may result in an adjustment to the estimated duration.

Under the Pliva Agreement, Indevus will be responsible for funding the development of the once-a-day formulation of SANCTURA. The Company is responsible for the manufacture of SANCTURA and will sell it to Pliva at cost. Pliva will be responsible for product inventory management and sales order fulfillment including billing and collecting of customer receivables. The Pliva Agreement is subject to termination by Pliva under certain circumstances. Under the Pliva Agreement, Indevus granted a security interest to Pliva in Indevus rights relating to FDA rights in SANCTURA and agreed to indemnify Pliva under certain circumstances.

For at least six months following the approval of SANCTURA, Indevus will receive a commission based on net sales of SANCTURA. During this period, Indevus will be responsible for funding its own sales force and certain advertising and promotional costs. Pliva and Indevus will co-promote SANCTURA through a joint sales force of approximately 500 sales representatives. Indevus will establish a sales force initially numbering approximately 280 representatives who will promote SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

At any time beginning six months after the approval of SANCTURA, each company has the right to convert the Pliva Agreement into a royalty-bearing structure, whereby Indevus will receive royalties from Pliva based on net sales of SANCTURA, and Pliva will be responsible for promotional and advertising costs. Should this right be exercised, Indevus specialty sales force will be subsidized by Pliva for a specified period, and will continue to promote SANCTURA to urology specialists, obstetricians and gynecologists, and high prescribers.

Pursuant to the NDA, the SANCTURA finished product is being manufactured by our licensor, Madaus AG (Madaus), at their manufacturing facility in Germany. We expect to launch SANCTURA in August 2004.

Aminocandin

In June 2004, we announced that aminocandin, under development as a treatment for systemic fungal infections, was well tolerated among healthy volunteers in a Phase I clinical trial and demonstrated a prolonged duration of antifungal activity following single-dose therapy. The trial was designed to test the safety and tolerance of rising single doses of intravenously administered aminocandin among approximately 40 healthy volunteers. Secondary objectives included the pharmacokinetic assessment of aminocandin in plasma and urine and determination of serum fungicidal activity. Dose levels achieved during this trial were approximately seven-fold higher than the anticipated clinical dose and were all well tolerated. Of particular note was the absence of infusion-related histamine reactions, a recognized effect of other drugs in the echinocandin class, and the lack of a significant infusion-associated rise in plasma histamine levels, even at the highest doses and concentrations of administered drug. Furthermore, following single intravenous doses, significant fungicidal activity was observed in patients serum samples for up to one week.

Citicoline

Effective January 22, 2004, we entered into a new agreement with 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.

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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 regularly 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.

Deferred Revenue

Pursuant to our revenue recognition policy, we recorded the initial payment and FDA-approval milestone received from Pliva as deferred revenue and are amortizing each of these components into revenue on a straight-line basis over the estimated remaining duration of the Pliva Agreement. Giving consideration to many factors, including patent issuances and lives, the potential for successful development of a once-a-day formulation of SANCTURA, competition, and technological change, we have estimated the duration of the Pliva agreement to be twelve years. We believe this is a significant judgment and estimate which will be re-evaluated when new information is presented that could affect this estimate. If we change our estimate of the duration of the Pliva Agreement in the future and extend or reduce our estimate of its duration, we would decrease or increase, respectively, the amount of periodic revenue recognized from the amortization of the deferred revenue.

Insurance Claim Receivable

As of June 30, 2004, 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 previously 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 June 30, 2004 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.

Significant Accounting Policy

Revenue pursuant to the Pliva Agreement will be recorded as follows: (i) the initial payment and the payment received upon FDA approval of SANCTURA twice daily are being amortized into revenue over the expected duration of the Pliva Agreement and future potential milestone payments will be amortized over the remaining expected duration of the Pliva Agreement commencing at the time the milestone was earned, (ii)

for at least the first six months following the approval of SANCTURA and prior to the conversion of the Pliva Agreement into a royalty-bearing structure, commissions earned on net sales of SANCTURA and reimbursement from Pliva of Pliva s share of promotion and advertising expenses incurred by us during the co-promotion period will be reflected as revenue, (iii) obligations to Pliva for our share of promotion and advertising expenses incurred by Pliva will be recorded as a reduction of revenue, (iv) subsequent to the conversion of the Pliva Agreement into a royalty-bearing structure, royalties on net sales of SANCTURA and the sales force subsidy will be recorded as revenue when earned, and (v) sales of SANCTURA to Pliva will be reflected as revenue upon shipment.

In evaluating the accounting for the Pliva Agreement we evaluated this multiple element arrangement under EITF 00-21, Accounting Revenue Arrangements with Multiple Deliverables. Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement.

The Company has concluded that fair value of its ongoing performance obligations described above does not exist and accordingly the entire arrangement will be accounted for as a single unit of accounting. This results in the up-front payment and milestone payments, once earned, being spread over the remaining life of the agreement and consideration contingent upon individual co-promotion services or delivery of units of product being recognized as earned.

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The Company evaluated EITF 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent, and EITF 01-09 Accounting for consideration Given by a Vendor to a Customer, and concluded that for advertising and promotion costs reimbursed by Pliva, because the Company is the primary obligor (i.e., we contract directly with vendors, negotiate terms and prices for services and goods and are obligated to pay for them regardless of reimbursement from Pliva) of such costs, amounts reimbursed will be recorded in revenue. In the event the Company is obligated to reimburse Pliva for promotion or advertising costs, the Company has concluded that such reimbursement is not sufficiently separable from the related revenues under the Pliva agreement and as such pursuant to EITF 01-09 will be recorded as a reduction of revenue.

On July 12, 2004, we filed with the SEC Post-Effective Amendment No. 4 to Form S-3 Registration Statement relating to our Convertible Senior Notes due July 15, 2008 to update the principle noteholder table as required. In connection with its review of this filing, the SEC reviewed and provided comments on certain of our 1934 Act filings, incorporated by reference thereto, including on our prospective accounting treatment for the Pliva Agreement. We have submitted a formal response to the SEC comment letter. While we believe we have accounted for the Pliva Agreement according to generally accepted accounting principles, the SEC may have a differing opinion which could cause us to account for the Pliva Agreement differently from how it is currently disclosed and reflected in this Form 10-Q.

Results of Operations

Our net loss increased $6,568,000 to $(18,618,000), or $(0.39) per share, basic, in the third quarter of fiscal 2004 from $(12,050,000), or $(0.26) per share, basic, in the third quarter of fiscal 2003 and increased $21,565,000 to $(42,012,000), or $(0.89) per share, in the nine month period ended June 30, 2004 from $(20,447,000), or $(0.44) per share, in the nine month period ended June 30, 2003. These increased net losses are primarily the result of our continuing development and pre-marketing activities related to SANCTURA.

Total revenues increased $2,092,000, or 293%, to $2,806,000 in the three month period ended June 30, 2004 from $714,000 in the three month period ended June 30, 2003 and increased $202,000, or 5%, to $4,609,000 in the nine month period ended June 30, 2004 from $4,407,000 in the nine month period ended June 30, 2003. Contract and license fees in the three and nine month periods ended June 30, 2004 relate almost entirely to the Pliva Agreement and include $1,470,000 from amortization of the deferred revenue and $851,000 net reimbursement due to the Company comprised of Pliva s share of SANCTURA promotion and advertising costs incurred by Indevus, less an amount owed by us to Pliva for Indevus share of SANCTURA promotion and advertising costs incurred by Pliva. Included in contract and license fees in the nine month period ended June 30, 2003 is a $777,000 initial payment received in from Lilly related to the renegotiated agreement with Lilly for Sarafem. Royalty revenue in the three and nine month periods ended June 30, 2004 and 2003 includes fixed net royalties received from Eli Lilly & Company (Lilly) for sales of Sarafem and the nine month period ended June 30, 2003 includes $2,184,000 of accelerated sales milestones which were one-time payments and do not recur. In the next fiscal quarter, we expect to record commissions on net sales of SANCTURA pursuant to the launch of SANCTURA and revenue from the sale of SANCTURA to Pliva.

Royalty expense decreased $59,000, or 38%, to $98,000 in the three month period ended June 30, 2004 from $157,000 in the three month period ended June 30, 2003 and decreased $445,000, or 49%, to $459,000 in the nine month period ended June 30, 2004 from $904,000 for the nine month period ended June 30, 2003. Royalty expense in the three and nine month periods ended June 30, 2004 and 2003 consists primarily of amounts due or paid to Massachusetts Institute of Technology for their portion of the royalties and contractual payments received from Lilly and decreased in the fiscal 2004 three and nine month periods as a result of decreased revenue from Sarafem as described above. We expect to record cost of revenues in the next fiscal quarter from sales of SANCTURA to Pliva.

Research and development expense decreased $2,953,000, or 34%, to $5,777,000 in the three month period ended June 30, 2004 from $8,730,000 in the three month period ended June 30, 2003 and increased $2,830,000, or 18%, to $18,636,000 in the nine month period ended June 30, 2004 from $15,806,000 in the nine month period ended June 30, 2003.

The decrease in research and development expense in the three month period is due primarily to decreased development costs related to SANCTURA and the absence of license and contractual fees paid in the fiscal 2003 three month period. SANCTURA development costs decreased approximately $3,100,000 due to absence of clinical costs and NDA preparation costs incurred in the fiscal 2003 three month period offset by once-a-day and other development costs that included a milestone payment to Shire, related to once-a-day development, of $1,250,000 incurred in the fiscal 2004 three month period. Additionally, the fiscal 2003 three month period included an initial license fee of $1,500,000 paid for aminocandin and a $500,000 contractual payment to Paligent, Inc. related to PRO 2000. The fiscal 2004 three month period also included other increased development costs of approximately $800,000 related primarily to dersalazine, aminocandin, and IP 751.

The increase in research and development expense in the nine month period is due primarily to increased development costs related to SANCTURA and the absence of license and contractual fees paid in the fiscal 2003 nine month period. SANCTURA

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development costs increased approximately $1,500,000 due to the QT study, once-a-day and other development costs offset by the absence of clinical costs and NDA preparation costs incurred in the fiscal 2003 nine month period and increased for milestone payments to Shire of $1,750,000 incurred in the fiscal 2004 nine month period. Additionally, the fiscal 2003 nine month period included an initial license fee of $1,500,000 paid for aminocandin and a $500,000 contractual payment to Paligent, Inc. related to PRO 2000. The fiscal 2004 nine month period also included other increased development costs of approximately $1,500,000 related primarily to IP 751, aminocandin, and of dersalazine. We expect to incur substantial costs related to SANCTURA as well as the continued development of our other products.

Marketing, general and administrative expense increased $10,596,000, or 266%, to $14,572,000 in the three month period ended June 30, 2004 from $3,976,000 in the three month period ended June 30, 2003 and increased $15,777,000, or 184%, to $24,370,000 in the nine month period ended June 30, 2004 from $8,593,000 in the nine month period ended June 30, 2003. The fiscal 2004 three month period included significant expenses related to the build-up of the sales force infrastructure in anticipation of the launch of SANCTURA. Sales and marketing expenses aggregated approximately $11,000,000 in the fiscal 2004 three month period, an increase of approximately $9,000,000 from the fiscal 2003 three month period. The Company expects to incur increased sales and marketing expenses through 2004. Additional increased expenses in the fiscal 2004 three month period over the fiscal 2003 three month period aggregated approximately $1,600,000 and included increased costs of consultants, staffing and facilities.

The increase in marketing, general and administrative expense in the nine month period primarily relates to the sales and marketing and support functions as described above. Of the $15,777,000 increase on a year to date basis, approximately 64% was incurred in the three month period ended June 30, 2004. Sales and marketing expenses aggregated approximately $17,000,000 in the fiscal 2004 nine month period, an increase of approximately $14,500,000 from the fiscal 2003 nine month period. Additional increased expenses in the fiscal 2004 nine month period over the fiscal 2003 nine month period aggregated approximately $1,300,000 and primarily included increased costs of consultants, staffing and facilities. We expect to incur increased sales and marketing expense in the next several quarters due to full staffing of the sales force and the launch and promotion of SANCTURA.

Investment income increased $216,000, or 218%, to $315,000 in the three month period ended June 30, 2004 from $99,000 in the three month period ended June 30, 2003 and increased $268,000, or 60%, to $717,000 in the nine month period ended June 30, 2004 from $449,000 in the nine month period ended June 30, 2003. The increases are due to higher average invested balances, offset somewhat by lower interest rates. Market interest rates have substantially decreased from the fiscal 2003 periods; however, due to the receipt of $150,000,000 in the three month period ended June 30, 2004 pursuant to the Pliva Agreement, average invested balances are substantially higher resulting in an increase in investment income.

Interest expense of $1,293,000 and $3,878,000 in the three and nine month periods ended June 30, 2004 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.

We expect to report losses from our current consolidated operations for fiscal 2004 and we expect an increased quarterly loss in the next fiscal quarter due primarily to significantly increased sales and marketing expenses related to SANCTURA.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At June 30, 2004, we had consolidated cash, cash equivalents and marketable securities of $192,567,000 compared to $84,087,000 at September 30, 2003. This increase of $108,480,000 was primarily the result of net cash provided by operating activities of $107,128,000 which included the receipt in the three month period ended June 30, 2004 of $150,000,000 pursuant to the Pliva Agreement.

We are continuing to invest substantial amounts in the ongoing development and sales and marketing activities related to SANCTURA. We are investing in the production of inventories of SANCTURA commencing in July 2004 and will sell the final product to Pliva at cost. We believe the funds received from Pliva under the Pliva Agreement will be sufficient to meet our obligations for the commercialization of SANCTURA. We believe we have sufficient cash for currently planned expenditures for the next twelve months.

We may 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 such be no assurance that, if such funds are required, we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If such additional funds are not obtained, we may be required to delay product development and business development activities.

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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 SANCTURA, including clinical trials to explore further certain attributes of SANCTURA and the development of extended release formulations and other development efforts. 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 for the manufacture of SANCTURA. In order to manufacture SANCTURA for sale in the United States, Madaus manufacturing facility must comply with cGMP requirements. Failure to meet or maintain compliance with cGMP requirements could cause a material disruption of, or cessation in, the commercialization of SANCTURA. We may seek a second source for SANCTURA if Madaus is unable to continue to meet all regulatory requirements or provide the necessary quantities of SANCTURA in a timely manner; this alternate source would require FDA approval which may or may not be obtained.

Total research and development expenses incurred by us through June 30, 2004 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: $68,700,000 for SANCTURA, $18,900,000 for pagoclone, $10,700,000 for PRO 2000, $2,600,000 for aminocandin and $2,700,000 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 June 30, 2004 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. 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 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 provided by operating activities for the nine month period ended June 30, 2004 of $107,128,000 consisted primarily of the $150,000,000 received from Pliva pursuant to the Pliva Agreement, which was classified as deferred revenue, and the net loss of $42,012,000. We paid $2,238,000 of interest due on our convertible notes in January 2004 and made a similar payment in July 2004.

Net cash used in investing activities of $8,148,000 is primarily due to net purchases of marketable securities. We expect to purchase marketable securities with a portion of the proceeds from the Pliva Agreement and use proceeds from maturities and sales of such securities to fund operations.

Net cash provided from financing activities of $1,947,000 resulted from net proceeds from the issuance of common stock upon the exercise of stock options. We cannot predict if or when stock options will be exercised in the future.

Other asset, noncurrent of $2,000,000 at June 30, 2004, represents an amount due to Madaus, and included in accrued expenses, pursuant to the Madaus Agreement as a result of receipt of the FDA approval to market SANCTURA. Pursuant to the Madaus Agreement, half of this amount will offset royalties due to Madaus on net sales of SANCTURA and one half will be amortized to cost of revenue over a period coincident with the expected term of the Pliva Agreement.

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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 SANCTURA tablets in bulk form to be used for the launch of the product. The current value of this purchase order is approximately $7,800,000, based upon recent exchange rates. In March 2004, we paid $2,000,000 to Madaus as a deposit on this order. We are committed to purchase from Madaus significant additional quantities of manufactured SANCTURA tablets in bulk form during the initial launch year. Pliva agreed to purchase from us commercial quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA.

We are currently negotiating an agreement to lease automobiles for our sales force. In addition, due to a substantial increase in employees, we are negotiating to lease additional office space.

Other

Recent Accounting Pronouncements

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 did not have a material impact on our financial position or results of operations.

EITF 03-6 was issued in March 2004 and is intended to clarify what is a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. ETIF 03-6 is effective for reporting periods beginning after March 31, 2004. The adoption of this pronouncement did not have an impact on our consolidated financial position, results of operations or cash flows.

Repurchase of Common Stock

On July 1, 2004, the Company announced that its board of directors has authorized the repurchase from time to time of up to 2,500,000 shares of its common stock in open market transactions. Through August 13, 2004, the Company has repurchased 1,166,000 shares at an average price of approximately $6.24 per share.

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.

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 $90. An increase in market interest rates could result in a decrease in the fair value of the Notes. For example on a very

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simplified basis, an interest rate increase of 1% could reduce the value of a $1000 Note by approximately $12. 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

As of June 30, 2004, 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 June 30, 2004. 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 control over financial reporting and there was no significant change in our internal control over financial reporting during the fiscal quarter ended June 30, 2004 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

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 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

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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.

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 April 19, 2004, the Company filed a current report on Form 8-K reporting that on April 7, 2004, the Company issued a press release announcing it entered into a License, Commercialization and Supply Agreement with Odyssey Pharmaceuticals Inc., the specialty branded subsidiary of PLIVA d.d. to commercialize SANCTURA (trospium chloride), then under review by the U.S. Food and Drug Administration as a treatment for overactive bladder.

On June 10, 2004, the Company filed a current report on Form 8-K reporting that (i) on May 28, 2004, the Company issued a press release announcing that the U.S. Food and Drug Administration approved SANCTURA and (ii) on June 2, 2004, the Company issued a press release announcing that it received a milestone payment of $120 million from PLIVA d.d. for the approval of SANCTURA by the U.S. Food and Drug Administration.

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INDEVUS PHARMACEUTICALS, INC.

INDEVUS PHARMACEUTICALS, INC

Date: August 16, 2004 By: /s/ Glenn L. Cooper

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

and Chief Executive Officer (Principal Executive Officer)

Date: August 16, 2004 By: /s/ Michael W. Rogers

Michael W. Rogers, Executive Vice President,

Chief Financial Officer and Treasurer (Principal Financial

Officer)

Date: August 16, 2004 By: /s/ Dale Ritter

Dale Ritter, Senior Vice President, Finance

(Principal Accounting Officer)