

INDEVUS PHARMACEUTICALS INC

Form 10-Q

May 10, 2005

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**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 March 31, 2005,

or

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

Commission File No. 0-18728

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**INDEVUS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of

04-3047911  
(I.R.S. Employer

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incorporation or organization)

Identification Number)

**One Ledgemont Center**

**99 Hayden Avenue**

**Lexington, Massachusetts**  
(Address of principal executive offices)

**02421-7966**  
(Zip Code)

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

<u>Class:</u>	<u>Outstanding at May 9, 2005</u>
<b>Common Stock \$.001 par value</b>	<b>46,997,109 shares</b>

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****INDEVUS PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)****(Amounts in thousands except share data)**

	<b>March 31,</b>	<b>September 30,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 93,071	\$ 127,099
Marketable securities	24,394	26,423
Accounts receivable	4,799	7,042
Inventories	651	1,160
Prepays and other current assets	3,014	3,082
	<u>          </u>	<u>          </u>
Total current assets	125,929	164,806
Marketable securities		3,486
Property and equipment, net	915	546
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	2,173	2,503
Other assets	1,160	1,239
	<u>          </u>	<u>          </u>
Total assets	\$ 131,435	\$ 173,838
	<u>          </u>	<u>          </u>
<b>LIABILITIES</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 3,314	\$ 6,361
Accrued expenses	10,805	13,707
Accrued interest	950	950
Deferred revenue	12,500	12,500
	<u>          </u>	<u>          </u>
Total current liabilities	27,569	33,518
Convertible notes	72,000	72,000
License fees payable	50	100
Deferred revenue	125,000	131,250
Minority interest	8	8
<b>STOCKHOLDERS DEFICIT</b>		
Preferred stock, \$.001 par value, 5,000,000 shares authorized;		
Series B, 239,425 shares issued and outstanding (liquidation preference at March 31, 2005 \$3,034)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at March 31, 2005 \$503)	500	500
	<u>          </u>	<u>          </u>
	48	48

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Common Stock, \$.001 par value, 80,000,000 shares authorized; 47,825,896 shares issued at March 31, 2005 and September 30, 2004

Additional paid-in capital	308,183	309,050
Accumulated deficit	(399,773)	(368,903)
Accumulated other comprehensive loss	(46)	(131)
Treasury stock, at cost, 828,787 and 1,057,125 shares at March 31, 2005 and September 30, 2004 respectively	(5,104)	(6,602)
<b>Total stockholders' deficit</b>	<b>(93,192)</b>	<b>(63,038)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 131,435</b>	<b>\$ 173,838</b>

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

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## INDEVUS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

For the three and six months ended March 31, 2005 and 2004

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended March 31,		Six months ended March 31,	
	2005	2004	2005	2004
<b>Revenues:</b>				
Product revenue	\$ 4,238	\$ 854	\$ 7,705	\$ 1,639
Contract and license fees	5,039	22	7,335	164
<b>Total revenues</b>	<b>9,277</b>	<b>876</b>	<b>15,040</b>	<b>1,803</b>
<b>Costs and expenses:</b>				
Cost of product revenue	3,375	209	5,855	524
Research and development	6,011	5,142	11,889	12,696
Marketing, general and administrative	8,187	5,782	25,668	9,798
<b>Total costs and expenses</b>	<b>17,573</b>	<b>11,133</b>	<b>43,412</b>	<b>23,018</b>
Loss from operations	(8,296)	(10,257)	(28,372)	(21,215)
Investment income	738	180	1,412	402
Interest expense	(1,293)	(1,293)	(2,585)	(2,585)
Impairment of equity securities	(175)		(175)	
Minority interest	1		1	4
<b>Loss before income taxes</b>	<b>(9,025)</b>	<b>(11,370)</b>	<b>(29,719)</b>	<b>(23,394)</b>
Provision for income taxes	(695)		(1,150)	
<b>Net loss</b>	<b>\$ (9,720)</b>	<b>\$ (11,370)</b>	<b>\$ (30,869)</b>	<b>\$ (23,394)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.21)</b>	<b>\$ (0.24)</b>	<b>\$ (0.66)</b>	<b>\$ (0.49)</b>
<b>Weighted average common shares outstanding:</b>				
Basic and diluted	46,967	47,397	46,946	47,304

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

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## INDEVUS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended March 31, 2005 and 2004

(Unaudited)

(Amounts in thousands)

	For the six months ended	
	March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	\$ (30,869)	\$ (23,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	173	12
Amortization of convertible note issuance costs	330	330
Impairment of equity securities	175	
Noncash compensation	75	
Changes in assets and liabilities:		
Accounts receivable	2,243	70
Inventories	509	
Prepaid and other assets	110	(3,178)
Accounts payable	(3,047)	(993)
Deferred revenue	(6,250)	
Accrued expenses and other liabilities	(2,974)	(879)
Net cash used in operating activities	(39,525)	(28,032)
Cash flows from investing activities:		
Purchases of property and equipment	(539)	(5)
Purchase of marketable securities		(3,210)
Proceeds from maturities and sales of marketable securities	5,462	19,302
Net cash provided by investing activities	4,923	16,087
Cash flows from financing activities:		
Net proceeds from issuance of common stock and treasury stock	574	1,591
Net cash provided by financing activities	574	1,591
Net change in cash and cash equivalents	(34,028)	(10,354)
Cash and cash equivalents at beginning of period	127,099	57,717
Cash and cash equivalents at end of period	\$ 93,071	\$ 47,363

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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, 2004.

Certain prior year amounts have been reclassified to conform to fiscal 2005 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 ( *OAB* ), and multiple compounds in clinical development.

*B. Revenue Recognition:*

Product revenue consists of revenues from sales of products, commissions, royalties and reimbursements from PLIVA d.d. ( *PLIVA* ), in accordance with our co-promotion and licensing agreement with Odyssey Pharmaceuticals, Inc., a specialty branded subsidiary of PLIVA (the *PLIVA Agreement* ), for royalties owed by the Company to Madaus A.G. ( *Madaus* ). Contract and license fee revenue consists of revenue stemming from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, reimbursements from PLIVA for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to PLIVA for the Company's share of SANCTURA promotion and advertising costs incurred by PLIVA, sales force subsidies from PLIVA, and grants from agencies supporting research and development activities.

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer.

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.

The Company's business strategy includes entering into 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 revenue when the Company has a contractual right to receive such payment, 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. The Company records such revenue as contract and license fee revenue.

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

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**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*B. Revenue Recognition (continued):*

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. Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. The Company records such revenue as contract and license fee revenue. Contractual subsidies of ongoing expenses are recorded as contract and license fee revenue.

Under the PLIVA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the Agreement to the time the milestone is earned over the estimated duration of the PLIVA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the PLIVA Agreement.

Multiple element arrangements are evaluated pursuant to EITF 00-21, Accounting Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and 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. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 ( SAB 104 ), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the PLIVA Agreement, the Company and PLIVA were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from PLIVA for PLIVA's share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for the Company's share were reflected as a reduction of contract and license fee revenue.

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

*C. Inventories*

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ( FIFO ) method.

The components of inventory are as follows:

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	March 31,	September 30,
	2005	2004
Raw materials	\$ 34,000	\$ 488,000
Finished goods	617,000	672,000
	<u>\$ 651,000</u>	<u>\$ 1,160,000</u>

Inventories consist solely of SANCTURA. Raw materials consist of tablets of SANCTURA in bulk form purchased from the Company's supplier, Madaus. Finished goods consist of SANCTURA tablets packaged in bottles for resale and blister packages for distribution as samples.

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**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*D. Basic and Diluted Loss per Common Share*

During the three month period ended March 31, 2005, 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 5,299,000 shares of Common Stock at prices ranging from \$4.35 to \$20.13 with expiration dates ranging up to December 7, 2014. Additionally, during the three month period ended March 31, 2005, 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 5,786,000 shares of Common Stock at prices ranging from \$1.22 to \$4.31 with expiration dates ranging up to March 10, 2015; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock and (iii) warrants to purchase 10,000 shares of Common Stock with an exercise price of \$6.19 and an expiration date of July 17, 2006.

During the three month period ended March 31, 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 524,000 shares of Common Stock at prices ranging from \$6.50 to \$20.13 with expiration dates ranging up to May 13, 2012. Additionally, during the three month period ended March 31, 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 9,468,000 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 six month period ended March 31, 2005, 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 4,761,000 shares of Common Stock at prices ranging from \$5.72 to \$20.13 with expiration dates ranging up to December 7, 2014. Additionally, during the six month period ended March 31, 2005, 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 6,202,000 shares of Common Stock at prices ranging from \$1.22 to \$5.38 with expiration dates ranging up to March 10, 2015; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock and (iii) warrants to purchase 10,000 shares of Common Stock with an exercise price of \$6.19 and an expiration date of July 17, 2006.

During the six month period ended March 31, 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; (ii) options to purchase 3,150,000 shares of Common Stock at prices ranging from \$6.00 to \$20.13 with expiration dates ranging up to May 13, 2012 and (iii) warrants to purchase 10,000 shares of Common Stock with exercise price of \$6.19 and with an expiration date of July 17, 2006. Additionally, during the six month period ended March 31, 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 6,949,000 shares of Common Stock at prices ranging from \$1.22 to \$5.93 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 45,000 shares of Common Stock with exercise prices ranging from \$5.00 to \$5.13 and with expiration dates ranging up to February 3, 2005.

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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.

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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		Six months ended	
	March 31,		March 31,	
	2005	2004	2005	2004
As reported net loss	\$ (9,720,000)	\$ (11,370,000)	\$ (30,869,000)	\$ (23,394,000)
Noncash compensation expense included in reported net income, net of tax	\$ 75,000	\$	\$ 75,000	\$
Compensation expense determined under the fair-value method for all awards, net of tax	\$ (670,000)	\$ (306,000)	\$ (1,346,000)	\$ (608,000)
Pro forma net loss	\$ (10,315,000)	\$ (11,676,000)	\$ (32,140,000)	\$ (24,002,000)
As reported net loss per common share:				
Basic	\$ (0.21)	\$ (0.24)	\$ (0.66)	\$ (0.49)
Diluted	\$ (0.21)	\$ (0.24)	\$ (0.66)	\$ (0.49)
Pro forma net loss per common share:				
Basic	\$ (0.22)	\$ (0.25)	\$ (0.68)	\$ (0.51)
Diluted	\$ (0.22)	\$ (0.25)	\$ (0.68)	\$ (0.51)

*F. Comprehensive Loss*

Comprehensive loss for the three and six month periods ended March 31, 2005 and 2004, respectively, is as follows:

	Three months ended		Six months ended	
	March 31,		March 31,	
	2005	2004	2005	2004
Net loss	\$ (9,720,000)	\$ (11,370,000)	\$ (30,869,000)	\$ (23,394,000)
Change in unrealized net gain or (loss) on investments	3,000	70,000	(53,000)	40,000

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Comprehensive loss	<u>\$ (9,717,000)</u>	<u>\$ (11,300,000)</u>	<u>\$ (30,922,000)</u>	<u>\$ (23,354,000)</u>
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**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*G. SANCTURA*

In April 2004, we entered into the PLIVA Agreement for the U.S. commercialization of SANCTURA (trospium chloride), which was launched in August 2004. Pursuant to the PLIVA Agreement, on September 27, 2004, the Company made formal notification to PLIVA with respect to the termination of the co-promotion period of the PLIVA Agreement, thereby converting the PLIVA Agreement into a royalty-bearing structure (the Conversion). The Conversion became effective on November 29, 2004 as of which date approximately 200 of the Company's primary care sales representatives became PLIVA employees. Under this royalty-bearing structure, the Company receives royalties from PLIVA based on net sales of SANCTURA, and PLIVA is responsible for promotional and advertising costs. Additionally, for the three years commencing November 29, 2004, PLIVA commenced subsidizing, at an annual rate of approximately \$7.7 million, the Company's specialty sales force which is continuing to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers.

Product revenues related to SANCTURA for the three month period ended March 31, 2005, consisted of \$3,015,000 from sales of bottles and samples of SANCTURA to PLIVA, \$639,000 of commissions and royalties from PLIVA on sales of SANCTURA, and \$160,000 of royalties due to Madaus for which PLIVA is contractually obligated to reimburse the Company. Product revenues related to SANCTURA for the six month period ended March 31, 2005, consisted of \$5,077,000 from sales of bottles and samples of SANCTURA to PLIVA, \$1,391,000 of commissions and royalties from PLIVA on sales of SANCTURA, and \$348,000 of royalties due to Madaus for which PLIVA is contractually obligated to reimburse the Company.

Contract and license fee revenue related to SANCTURA in the three month period ended March 31, 2005 consisted of \$3,125,000 from amortization of the deferred revenue, \$1,920,000 for the sales force subsidy from PLIVA. Contract and license fee revenue related to SANCTURA in the six month period ended March 31, 2005 consisted of \$6,250,000 from amortization of the deferred revenue, \$2,560,000 for the sales force subsidy from PLIVA less \$1,489,000 net reimbursement due to PLIVA comprised of \$2,683,000 of PLIVA's share of SANCTURA promotion and advertising costs incurred by Indevus, less \$4,172,000 owed by the Company to PLIVA for our share of SANCTURA promotion and advertising costs incurred by PLIVA.

On April 30, 2005, the Company and PLIVA clarified and amended certain provisions of the PLIVA Agreement relating to royalties payable on sales of SANCTURA. The amendment provides for Indevus to receive increased royalty payments based on a revised calculation methodology up to a defined amount in exchange for our simultaneous contribution of a portion of these payments toward Phase IV clinical studies planned or being conducted by PLIVA. The aggregate increase in royalties under the revised methodology versus the current methodology, net of the Company's contribution to Phase IV, is expected to be approximately \$700,000. The Company expects to record this amount as revenue over the next two fiscal quarters.

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

In May 2001, the Company entered into the AHP Indemnity and Release Agreement 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

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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 financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the Company's defense costs were paid by, or subject to reimbursement to the Company from, the Company's product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Indevus by Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth's national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

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**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of March 31, 2005, the Company had an outstanding insurance claim of \$3,735,000, 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 has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$1,258,000 reflected as a noncurrent insurance claim receivable at March 31, 2005. It is uncertain when, if ever, the Company will collect any of its \$3,735,000 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 March 31, 2005, the Company has an accrued liability of approximately \$600,000 for Redux-related expenses, including legal expenses. The amounts the Company ultimately pays could differ from this amount. To the extent amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

*I. Income taxes*

The provision for income taxes of \$695,000 for the three month period ended March 31, 2005 and of \$1,150,000 for the six month period ended March 31, 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received from PLIVA in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

*J. Investment in Aeolus*

In the three and six months periods ended March 31, 2005, the Company recorded a charge for impairment of equity securities of \$175,000 to reflect a write down of the Company's investment in Aeolus Pharmaceuticals, Inc. ( "Aeolus" ) to fair value as the decline in Aeolus stock was deemed other than temporary.

*K. Facilities Lease*

In December 2004, the Company entered into a lease agreement for new corporate headquarters in Lexington, MA. This lease for approximately 45,000 square feet provides for an initial term of 66 months, commencing upon occupancy. The aggregate minimum rental commitment is approximately \$5,400,000. The Company expects to occupy its new facilities in June 2005, prior to the April 2007 expiration of the lease period of its current facilities. The Company expects to record a charge related to the future nonutilization of its current facilities in the period when the

Company ceases to use such facilities.

*L. Recent Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board ( FASB ) issued its Statement of Financial Accounting No. 123 (revised 2004), Share-Based Payments ( SFAS No. 123R ), which revises Statement of Financial Accounting Standard No. 123, Accounting for Stock-Based Compensation and requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Under SFAS 123R, the most significant change in practice would be treating the fair value of stock-based payment awards that are within its scope as compensation expense in the income statement beginning on the date that a company grants the awards to employees. In April 2005, the effective date for this accounting standard was deferred until the first annual period beginning after June 15, 2005. The Company will adopt SFAS No. 123R in the reporting period starting October 1, 2005. The Company is currently assessing the impact that the adoption of this standard will have on its financial position and 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 (the Exchange Act ), and the Private

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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 Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions. The words believe, expect, anticipate, intend, plan, estimate, expressions which predict or indicate future events and trends and do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company's Form 10-K for the fiscal year ended September 30, 2004. These factors include, but are not limited to: dependence on the success of SANCTURA® and SANCTURA XR (once-a-day SANCTURA); the early stage of products under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA and SANCTURA XR; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; 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. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements.

The following discussion should be read in conjunction with our 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, 2004. Unless the context indicates otherwise, Indevus, the Company, we, our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock refers to the common stock, \$.001 par value per share, of Indevus. SANCTURA and SANCTURA XR are registered trademarks of Indevus.

## **Description of the Company**

Indevus Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the acquisition, development and commercialization of products targeting certain medical specialty areas, including urology and infectious diseases. We currently market SANCTURA for overactive bladder and have multiple compounds in clinical development, including pagoclone for stuttering, aminocandin for systemic fungal infections, PRO 2000 for the prevention of infection by HIV and other sexually transmitted pathogens, and IP 751 for pain and inflammatory disorders such as interstitial cystitis.

## **Recent Product Developments**

### **SANCTURA**

In April 2004, we entered into the PLIVA Agreement for the U.S. commercialization of SANCTURA (trospium chloride) launched in August 2004. Pursuant to the PLIVA Agreement, we made formal notification to PLIVA with respect to the termination of the six-month co-promotion period of the Agreement, thereby converting the Agreement into a royalty-bearing structure (the Conversion). The Conversion became effective on November 29, 2004, as of which date approximately 200 of our primary care sales representatives became PLIVA employees. Under this royalty-bearing structure, we receive royalties from PLIVA based on net sales of SANCTURA, and PLIVA is responsible for promotional and advertising costs. Additionally, for the three years commencing November 29, 2004, PLIVA commenced subsidizing, at an annual rate of approximately \$7.7 million, our specialty sales force, which is continuing to promote SANCTURA to urology specialists, obstetricians and gynecologists, and other high prescribers.

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A Phase III trial for SANCTURA XR is scheduled to commence in the summer of 2005. Pursuant to the PLIVA Agreement, we are due a \$10,000,000 payment upon the achievement of this milestone. We currently expect to file an NDA for SANCTURA XR in the second half of calendar 2006.

### Aminocandin

In October 2004, we commenced a multi-dose Phase I trial of aminocandin. During dose escalation, we saw some local vein irritation as doses and concentrations increased causing us to interrupt the trial. We believe we have identified the formulation issues that caused such vein irritation and we are currently working on a reformulation of the intravenous dosage form. Overall, the product continues to have a favorable systemic safety profile. We plan to restart the Phase I study later in 2005.

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### PRO 2000

A National Institutes of Health ( NIH )-sponsored Phase II/III clinical trial to assess the safety and effectiveness of PRO 2000 in blocking male to female HIV transmission began in February 2005 at sites in Africa and the U.S. The study involves approximately 3,220 HIV-uninfected women, most of whom are at risk for acquiring HIV by virtue of living in regions where the infection rate is high. The trial will also evaluate effectiveness against other sexually transmitted diseases.

A Phase III trial, sponsored by the Medical Research Council, is designed to test the safety and effectiveness of PRO 2000 for preventing HIV infection and other sexually transmitted infections in women, is expected to begin in the summer of 2005 in four African countries. This study is expected to run for approximately 39 months and to include approximately 12,000 women.

In February 2005, findings from a study performed at the Mount Sinai School of Medicine were presented at the 12<sup>th</sup> Conference on Retroviruses and Opportunistic Infections. These data demonstrated that PRO 2000 retains activity against the human immunodeficiency virus (HIV) and the herpes simplex virus (HSV) following intravaginal administration to HIV-infected women. The study, funded by the NIH, marks the first time that the anti-viral activity of a microbicide has been demonstrated following human application.

### Pagoclone

We are planning to commence a Phase II trial for pagoclone in stuttering by mid-2005. We expect to have results from this study in late 2005 or early next year.

### IP 751

In March 2005, we announced the results of a study conducted at the University of Pittsburgh that showed that administration of IP 751, a novel synthetic cannabinoid, significantly reduces the bladder overactivity observed in an animal model of interstitial cystitis. IP 751 suppressed the overactivity in a dose dependent manner and at the highest dose completely reversed the excessive bladder contractility to normal function. In addition, IP 751 appeared to have no effect on the normal voiding mechanism of the bladder. We have now completed a second study confirming these results.

## **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

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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.

### *Expected Term of the PLIVA Agreement and Deferred Revenue*

The initial \$30 million payment received from PLIVA and the \$120 million payment received from PLIVA upon receipt of FDA approval to market SANCTURA are significant and we are recording the initial and milestone payments received from PLIVA as deferred revenue and amortizing each of these components into revenue under the contingency adjusted method over the estimated duration of the PLIVA Agreement commencing on the date earned. We believe our estimated twelve-year term of the PLIVA Agreement is a significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet.

We amortized \$3,125,000 of deferred revenue into contract and license fee revenue in the three months ended March 31, 2005 and \$6,250,000 for the six months ended March 31, 2005. The balance of deferred revenue at March 31, 2005 is \$137,500,000. We will reevaluate our estimate of the expected term of the PLIVA Agreement when new information is known 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 to be recognized from the amortization of remaining deferred revenue.

### *Insurance Claim Receivable*

As of March 31, 2005, 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 March 31, 2005 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.



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### *Redux-Related Liabilities*

At March 31, 2005, we have an accrued liability of approximately \$600,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at March 31, 2005. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

### **Significant Accounting Policy**

*Revenue Recognition:* Product revenue consists of revenues from sales of products, commissions, royalties and reimbursements from PLIVA for royalties owed by the Company to Madaus. Contract and license fee revenue consists of revenue stemming from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, reimbursements from PLIVA for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to PLIVA for the Company's share of SANCTURA promotion and advertising costs incurred by PLIVA, sales force subsidies from PLIVA, and grants from agencies supporting research and development activities.

We record sales of product as product revenue upon the later of shipment or as title passes to its customer. In fiscal 2004, we commenced selling SANCTURA to PLIVA in bottles for resale and blister packs for distribution as samples.

Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and are generally reported to us 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 we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, in which case we recognize such royalty revenue in the subsequent accounting period when we receive the royalty report and 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.

Our business strategy includes entering into collaborative license and development or co-promotion agreements with strategic partners for the development and commercialization of our 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 revenue when we have a contractual right to receive such payment, 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 arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as we complete our 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. We record such revenue as contract and license fee revenue.

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

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achievement of the related milestone. We record such revenue as contract and license fee revenue. Contractual subsidies of ongoing expenses are recorded as contract and license fee revenue.

Under the PLIVA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the PLIVA Agreement to the time the milestone is earned over the estimated duration of the PLIVA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the PLIVA Agreement.

Multiple element arrangements are evaluated pursuant to EITF 00-21, Accounting Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the

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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. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104 ( SAB 104 ), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the PLIVA Agreement, the Company and PLIVA were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by us, reimbursements from PLIVA for PLIVA's share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by PLIVA, reimbursements to PLIVA for our share are reflected as a reduction of contract and license fee revenue.

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

**Results of Operations**

Our net loss decreased \$1,650,000 to \$(9,720,000), or \$(0.21) per share, basic, in the three month period ended March 31, 2005 from \$(11,370,000), or \$(0.24) per share, basic, in the three month period ended March 31, 2004 and increased \$7,475,000 to \$(30,869,000) in the six month period ended March 31, 2005 from \$(23,394,000) in the six month period ended March 31, 2004. The decreased loss in the three month period is primarily due to revenue, net of cost, related to the PLIVA Agreement recognized in fiscal 2005 partially offset by increased marketing, general and administrative and research and development expenses as described below. The increased net loss in the six month period is primarily the result of significantly increased marketing activities related to SANCTURA, including costs related to our SANCTURA sales force, partially offset by increased revenue, net of cost, related to the PLIVA Agreement recognized in fiscal 2005 as described below.

Total revenues increased \$8,401,000, or 959%, to \$9,277,000 in the three month period ended March 31, 2005 from \$876,000 in the three month period ended March 31, 2004 and \$13,237,000, or 734%, to \$15,040,000 in the six month period ended March 31, 2005 from \$1,803,000 in the six month period ended March 31, 2004, due to SANCTURA-related revenues that did not exist in the three and six month periods ended March 31, 2004.

Product revenue increased \$3,384,000, or 396%, to \$4,238,000 in the three month period ended March 31, 2005 from \$854,000 in the three month period ended March 31, 2004 and \$6,066,000, or 370%, to \$7,705,000 in the six month period ended March 31, 2005 from \$1,639,000 in the six month period ended March 31, 2004. Product revenue in the three month period ended March 31, 2005 included \$3,015,000 from sales of SANCTURA to PLIVA, \$799,000 of royalties from PLIVA on sales of SANCTURA, including \$160,000 of royalties due to Madaus, and \$422,000 of royalties from Eli Lilly & Company ( Lilly ) on sales of Sarafem. Product revenue in the three month period ended March 31, 2004 of \$854,000 consisted of royalties from Lilly on sales of Sarafem. Product revenue in the six month period ended March 31, 2005 included \$5,077,000 from sales of SANCTURA to PLIVA, \$1,739,000 of royalties from PLIVA on sales of SANCTURA, including \$348,000 of royalties due to Madaus, and \$887,000 of royalties from Lilly on sales of Sarafem. Product revenue in the six month period ended March 31, 2004 of \$1,639,000 consisted of royalties from Lilly on sales of Sarafem.

Contract and license fee revenue of \$5,039,000 and \$7,335,000 in the three and six month periods ended March 31, 2005, respectively, relate almost entirely to the PLIVA Agreement. Contract and license fee revenue in the three month period ended March 31, 2005 include \$3,125,000 from amortization of the deferred revenue and \$1,920,000 for three months of sales force subsidy from PLIVA. Contract and license fee revenue in the six month period ended March 31, 2005 include \$6,250,000 from amortization of the deferred revenue and \$2,560,000 for four months of sales force subsidy from PLIVA less \$1,489,000 net reimbursement due to PLIVA comprised of \$2,683,000 of PLIVA's share of SANCTURA promotion and advertising costs incurred by Indevus, less \$4,172,000 owed by us to PLIVA for our share of SANCTURA promotion and advertising costs incurred by PLIVA. Contract and license fee revenue of \$164,000 in the six month period ended March 31, 2004 relates

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primarily to a research grant for certain PRO 2000 development costs.

Cost of product revenue of \$3,375,000 and \$5,855,000 in the three and six month periods ended March 31, 2005, respectively, relates primarily to sales of SANCTURA which we sell to PLIVA at our cost. Also included in cost of product revenue in the three and six month periods ended March 31, 2005 are \$160,000 and \$348,000, respectively, of royalties to Madaus. Cost of product revenue of \$209,000 and \$524,000 in the three and six month periods ended March 31, 2004, respectively, includes \$171,000 and \$328,000, respectively, of royalties due to the Massachusetts Institute of Technology for their portion of the Sarafem royalties.

Research and development expense increased \$869,000, or 17%, to \$6,011,000 in the three month period ended March 31, 2005 from \$5,142,000 in the three month period ended March 31, 2004 and decreased \$807,000, or 6%, to \$11,889,00 in the six month period ended March 31, 2005 from \$12,696,000 in the six month period ended March 31, 2004. Increased

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external product development costs of approximately \$1,600,000 in the three month period related to aminocandin, PRO 2000, IP 751 and pagoclone due to increased development activities were offset by approximately \$1,200,000 decreased external product development costs related to trospium which was primarily due to a Phase III study and our QT study which ended in fiscal 2004. Additionally contributing to the increase in the three month period was increased staffing and related support costs of approximately \$300,000. The decrease in the six month period included a \$4,100,000 decrease of external product development costs related to trospium, which was primarily due to a Phase III study and our QT study which ended in fiscal 2004, offset by a net increase of external product development costs of approximately \$2,100,000 related to aminocandin, PRO 2000, IP 751 and pagoclone and a \$750,000 development milestone related to aminocandin. Additionally, the six month period increase reflected increased staffing and related support costs of approximately \$600,000 and the six month period ended March 31, 2004 included a \$500,000 development milestone related to PRO 2000.

Marketing, general and administrative expense increased \$2,405,000, or 42%, to \$8,187,000 in the three month period ended March 31, 2005 from \$5,782,000 in the three month period ended March 31, 2004 and increased \$15,870,000, or 162%, to \$25,668,00 in the six month period ended March 31, 2005 from \$9,798,000 in the six month period ended March 31, 2004.

Marketing expenses increased \$882,000, or 23%, to \$4,681,000 in the three month period ended March 31, 2005 from \$3,799,000 in the three month period ended March 31, 2004. This increase reflected significantly increased costs related to our approximately 85-person specialty sales force and related infrastructure which had not been established in the three month period ended March 31, 2004. Substantially offsetting the increased sales force costs are significantly reduced promotion and advertising expenses related to SANCTURA because we had incurred such costs prior to the PLIVA Agreement and subsequent to the Conversion, Odyssey has been responsible for such costs.

Marketing expenses increased \$13,384,000, or 225%, to \$19,323,000 in the six month period ended March 31, 2005 from \$5,939,000 in the six month period ended March 31, 2004. This increase reflected significantly increased costs related to our approximately 85-person specialty sales force and related infrastructure which was in place for all six months of fiscal 2005 and the approximately 200-person primary care sales force which was in place for the first two months of fiscal 2005, none of which was in place in the six month period ended March 31, 2004. Also contributing to the increase were higher promotion and advertising expenses related to SANCTURA, a substantial portion of which was incurred during the copromotion period prior to the Conversion.

General and administrative expenses increased \$1,523,000, or 77%, to \$3,506,000 in the three month period ended March 31, 2005 from \$1,983,000 in the three month period ended March 31, 2004 and increased \$2,486,000, or 64%, to \$6,345,000 in the six month period ended March 31, 2005 from \$3,859,000 in the six month period ended March 31, 2004. Increased costs in the three and six month periods ended March 31, 2005 include approximately \$800,000 and \$1,200,000, respectively, of personnel and support costs due to the increased number of employees required to support our increased business activities and increased consulting and accounting fees related to our implementation of Sarbanes-Oxley-required accounting and reporting control systems and tax compliance and other costs related to our expanded business activities.

Investment income increased \$558,000, or 310%, to \$738,000 in the three month period ended March 31, 2005 from \$180,000 in the three month period ended March 31, 2004 and increased \$1,010,000, or 251%, to \$1,412,000 in the six month period ended March 31, 2005 from \$402,000 in the six month period ended March 31, 2004. These increases are due to higher average invested balances and increased interest rates.

Interest expense relates to our \$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.

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Impairment of equity securities of \$175,000 in the three and six month periods ended March 31, 2005 reflect a write down of our investment in Aeolus to fair value as the decline in Aeolus common stock was deemed other than temporary.

The provision for income taxes of \$695,000 and \$1,150,000 in the three and six month periods ended March 31, 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received from PLIVA in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

On April 30, 2005, we and PLIVA clarified and amended certain provisions of the PLIVA Agreement relating to royalties payable on sales of SANCTURA. The amendment provides for us to receive increased royalty payments based on a revised calculation methodology up to a defined amount in exchange for our simultaneous contribution of a portion of these

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payments toward Phase IV clinical studies planned or being conducted by PLIVA. The aggregate increase in royalties under the revised methodology versus the current methodology, net of our contribution to Phase IV, is expected to be approximately \$700,000. We expect to record this amount as revenue over the next two fiscal quarters.

We expect to report losses from our current consolidated operations for fiscal 2005.

## **Liquidity and Capital Resources**

### **Cash, Cash Equivalents and Marketable Securities**

At March 31, 2005 we had consolidated cash, cash equivalents and marketable securities of \$117,465,000 compared to \$157,008,000 at September 30, 2004. This decrease of \$39,543,000 was primarily the result of net cash used in operating activities of \$39,525,000 (see "Analysis of Cash Flows").

We are continuing to invest substantial amounts in the ongoing development and sales activities related to SANCTURA. We are investing in the production of inventories of SANCTURA and are selling 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 at least 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 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.

### **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, SANCTURA XR, and other related development efforts. We could receive up to \$45 million in future payments contingent upon the achievement of certain milestones related to the development of SANCTURA XR. Additionally, after November 28, 2004 and pursuant to the Conversion, PLIVA is responsible for funding certain Phase IV studies that may be conducted. 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 U.S. 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.

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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 March 31, 2005 on the major compounds currently being developed or marketed, including allocation of corporate general and administrative expenses, are approximately as follows: \$87,600,000 for SANCTURA, \$20,300,000 for pagoclone, \$13,700,000 for PRO 2000, \$7,600,000 for aminocandin and \$3,900,000 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



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allocation of corporate general and administrative expenses, from March 31, 2005 through the preparation of an NDA for our major compounds currently being developed as follows: approximately \$16,000,000 for PRO 2000, approximately \$76,000,000 for aminocandin, and approximately \$45,000,000 for pegoclone. For IP751, we are unable at this time to estimate the costs to completion of development. IP751 is in pre-clinical testing as an agent for interstitial cystitis. We are currently evaluating different dosage forms and different routes of administration for the compound. Once we have made further decisions regarding the development for IP751, we expect to be able to estimate the costs for the compound through the preparation of an NDA. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development.

### Analysis of Cash Flows

Cash used in operating activities for the six month period ended March 31, 2005 of \$39,525,000 consisted primarily of the net loss of \$30,869,000 and \$6,250,000 amortization of deferred revenue from contractual payments received from PLIVA in fiscal 2004. Additionally, uses of cash resulted from a \$3,047,000 reduction of accounts payable due to reduced operating expenses from the cessation promotion and advertising pursuant to the Conversion and general timing of payments, and a \$2,974,000 reduction of accrued expenses and other liabilities resulting primarily from reduced inventory due to a reduced rate of production of SANCTURA and the cessation of promotion and advertising costs pursuant to the Conversion, partially offset by increased accruals related to research and development activities and other operating activities. A \$2,243,000 source of cash related to a net reduction of accounts receivable due to collections from PLIVA.

Net cash provided by investing activities of \$4,923,000 is primarily due to net maturities and sales of marketable securities of \$5,462,000 net of \$539,000 of capital expenditures.

Net cash provided from financing activities of \$574,000 resulted from net proceeds primarily from the issuance of treasury stock upon the exercise of stock options. We cannot predict if or when stock options will be exercised in the future.

### Commitments

Pursuant to the supply agreement with Madaus, we have committed to purchase from Madaus a certain minimum quantity of manufactured SANCTURA tablets in bulk form through the SANCTURA Launch Year which ends in August 2005. The current value of this commitment is approximately \$2,100,000 based upon recent exchange rates. If such minimum quantities are not purchased, we would owe Madaus a fee. PLIVA agreed to purchase from us commercial quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and any fees to Madaus resulting from purchases below our committed minimum quantity.

In December 2004, we entered into a lease agreement for new corporate headquarters in Lexington, MA. This lease for approximately 45,000 square feet provides for an initial term of 66 months, commencing upon occupancy. Lease payments commence six months after occupancy and the aggregate minimum rental commitment is approximately \$5,400,000. We expect to occupy our new facilities in June 2005, prior to the April 2007 expiration of the lease period of our current facilities. The Company expects to record a charge related to the future nonutilization of our current facilities in the period when we cease to use them.

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We have entered into a lease agreement to lease approximately 90 automobiles for our field sales force. The lease requires a minimum term of 12 months per automobile. We expect monthly lease expense related to this operating lease to be approximately \$50,000. We are responsible for certain disposal costs in case of termination.

### **Other**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued its Statement of Financial Accounting No. 123 (revised 2004), Share-Based Payments ( SFAS No. 123R ), which revises Statement of Financial Accounting Standard No. 123, Accounting for Stock-Based Compensation and requires companies to expense the fair value of employee stock options and other forms of stock-based compensation. Under SFAS 123R, the most significant change in practice would be treating the fair value of stock-based payment awards that are within its scope as compensation expense in the income statement beginning on the date that a company grants the awards to employees. In April 2005, the effective date for this accounting standard was deferred until the first annual period beginning after June 15, 2005. The Company will adopt SFAS No. 123R in the reporting period starting October 1, 2005. We are currently assessing the impact that the adoption of this standard will have on our financial position and results of operations.

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### ***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 \$20. 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***

As of March 31, 2005 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 March 31, 2005. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective. 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 March 31, 2005 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

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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 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 4. Submission of Matters to a Vote of Security Holders***

The Company's annual meeting of stockholders was held on March 9, 2005. At the meeting (i) all seven director nominees were elected; (ii) the amendment to the Company's Restated Certificate of Incorporation as amended to increase the number of authorized shares was approved; (iii) the Company's 1995 Employee Stock Purchase Plan was amended and (iv) the appointment of PricewaterhouseCoopers LLP as the Company's independent auditors was ratified.

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- (i) The following Directors were elected for a one-year term by the votes indicated: Glenn L. Cooper, M.D., 41,567,815 for, 1,210,110 against; Harry J. Gray, 41,242,925 for, 1,535,000 against; Michael E. Hanson 41,652,790 for, 1,125,135 against; Stephen C. McCluski, 41,682,315 for, 1,095,610 against; Cheryl P. Morley, 41,678,822 for, 1,099,103 against; Malcolm Morville, Ph.D., 41,280,197 for, 1,497,728 against; and David B. Sharrock, 41,088,127 for, 1,687,798 against.
  
- (ii) The amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares was approved by (a) the holders of the Company's Common Stock and Preferred Stock voting on a fully converted basis by a vote of 41,789,281 for, 1,409,735 against 147,759 abstaining, and 0 broker non-votes, and (b) the holders of the Company's Common Stock voting separately as a single class by a vote of 41,220,431 for, 1,409,735 against, 147,759 abstaining, and 0 broker non-votes.

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- (iii) The amendment to increase the number of shares available for purchase under the Company's 1995 Employee Stock Purchase Plan was approved by a vote of 15,297,589 for, 2,001,849 against, 123,582 abstaining, and 25,923,755 broker non-votes.
- (iv) The appointment of PricewaterhouseCoopers LLP was ratified by a vote of 42,455,386 for, 792,206 against, 99,183 abstaining, and 0 broker non-votes.

***Item 5. Other Information***

On December 20, 2004, we entered into a lease agreement with Boston Properties Limited Partnership for new corporate headquarters at 33 Hayden Avenue in Lexington, MA. This lease for approximately 45,000 square feet provides for an initial term of 66 months, commencing upon occupancy. We expect to occupy our new facilities in June 2005.

***Item 6. Exhibits***

(a) Exhibits

- 10.143 Amendment #1 to PLIVA License, Commercialization and Supply Agreement dated as of April 30, 2005 by and between Indevus Pharmaceuticals, Inc. and Odyssey Pharmaceuticals, Inc. (1)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer

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- (1) Confidentiality requested for a portion of this agreement.

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**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC

Date: May 10, 2005

By: /s/ Glenn L. Cooper

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

Date: May 10, 2005

By: /s/ Michael W. Rogers

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

Date: May 10, 2005

By: /s/ Dale Ritter

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