

INDEVUS PHARMACEUTICALS INC

Form 10-Q

May 12, 2004

Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

---

**FORM 10-Q**

---

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

For the quarterly period ended March 31, 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  
(State or other jurisdiction of

incorporation or organization)

One Ledgemont Center

04-3047911  
(I.R.S. Employer

Identification Number)

02421-7966

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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  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 7, 2004</u>
Common Stock \$.001 par value	47,707,496 shares

---

---

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

**INDEX TO FORM 10-Q**

	<b>PAGE</b>
	<b>_____</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements</u>	
<u>Consolidated Balance Sheets as of March 31, 2004 and September 30, 2003</u>	3
<u>Consolidated Statements of Operations for the Three and Six Months ended March 31, 2004 and 2003</u>	4
<u>Consolidated Statements of Cash Flows for the Three and Six Months ended March 31, 2004 and 2003</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	14
Item 4. <u>Controls and Procedures</u>	15
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	15
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	16
Item 6. <u>Exhibits and Reports on Form 8-K</u>	17
<u>SIGNATURES</u>	18

**Table of Contents****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>2004</b>	<b>2003</b>
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,363	\$ 57,717
Marketable securities	10,273	26,370
Accounts receivable	85	155
Prepays and other current assets	4,419	1,241
	<u>          </u>	<u>          </u>
Total current assets	62,140	85,483
Investment in equity securities	179	134
Property and equipment, net	26	33
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	2,833	3,163
	<u>          </u>	<u>          </u>
Total assets	<u>\$ 66,436</u>	<u>\$ 90,071</u>
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$ 965	\$ 1,958
Accrued expenses	7,901	8,721
Accrued interest	950	938
	<u>          </u>	<u>          </u>
Total current liabilities	9,816	11,617
Convertible Notes	72,000	72,000
License fees payable	150	200
Minority interest	9	13
<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, 2004 \$3,034);	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at March 31, 2004 \$503)	500	500
Common stock, \$.001 par value, 80,000,000 shares authorized; 47,673,114 and 47,175,661 shares issued and outstanding at March 31, 2004 and September 30, 2003, respectively	48	47
Additional paid-in capital	305,025	303,452
Accumulated deficit	(324,085)	(300,691)
Accumulated other comprehensive loss	(27)	(67)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Total stockholders' equity (deficit)	<u>(15,539)</u>	<u>6,241</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 66,436</u>	<u>\$ 90,071</u>

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

Table of Contents

## INDEVUS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

For the three and six months ended March 31, 2004 and 2003

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended		Six months ended	
	March 31,		March 31,	
	2004	2003	2004	2003
Revenues:				
Royalty revenue	\$ 854	\$ 2,857	\$ 1,639	\$ 2,857
Contract and license fees	22	14	164	836
Total revenues	876	2,871	1,803	3,693
Costs and expenses:				
Cost of revenues	209	596	524	806
Research and development	5,142	3,240	12,696	7,017
Marketing, general and administrative	5,782	2,160	9,798	4,617
Total costs and expenses	11,133	5,996	23,018	12,440
Loss from operations	(10,257)	(3,125)	(21,215)	(8,747)
Investment income	180	159	402	350
Interest expense	(1,293)		(2,585)	
Minority interest			4	
Net loss	\$ (11,370)	\$ (2,966)	\$ (23,394)	\$ (8,397)
Net loss per common share:				
Basic and diluted	\$ (0.24)	\$ (0.06)	\$ (0.49)	\$ (0.18)
Weighted average common shares outstanding:				
Basic and diluted	47,397	46,886	47,304	46,881

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

Table of Contents

## INDEVUS PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended March 31, 2004 and 2003

(Unaudited)

(Amounts in thousands)

	Six months ended	
	March 31,	
	2004	2003
Cash flows from operating activities:		
Net loss	\$ (23,394)	\$ (8,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	12	8
Amortization of debt issuance costs	330	
Minority interest in net income of consolidated subsidiary	(4)	
Change in assets and liabilities:		
Accounts receivable	70	481
Prepaid and other assets	(3,178)	(1,527)
Accounts payable	(993)	1,529
Accrued expenses and other liabilities	(875)	229
Net cash used in operating activities	<u>(28,032)</u>	<u>(7,677)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(3,210)	(3,877)
Proceeds from maturities and sales of marketable securities	19,302	14,732
Capital expenditures	(5)	(10)
Net cash provided by investing activities	<u>16,087</u>	<u>10,845</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock	1,591	66
Net cash provided by financing activities	<u>1,591</u>	<u>66</u>
Net change in cash and cash equivalents	(10,354)	3,234
Cash and cash equivalents at beginning of period	57,717	19,977
Cash and cash equivalents at end of period	<u>\$ 47,363</u>	<u>\$ 23,211</u>
Supplemental information:		
Interest paid	<u>\$ 2,238</u>	<u>\$</u>

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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



---

**Table of Contents**

**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.

Indevus is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late-stage clinical development.

*B. Basic and Diluted Loss per Common Share*

During the three month period ended 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 three month period ended March 31, 2003, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) options to purchase 9,292,596 shares of Common Stock at prices ranging from \$2.15 to \$20.13 with expiration dates ranging up to March 12, 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 March 31, 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 857,639 shares of Common Stock at prices ranging from \$1.22 to \$2.06 with expiration dates ranging up to October 8, 2012 and (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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.

During the six month period ended March 31, 2003, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were as follows: (i) options to purchase 9,557,383 shares of Common Stock at prices ranging from \$2.15 to \$20.13 with expiration dates ranging up to March 12, 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 six month period ended March 31, 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

**Table of Contents**

the period, were as follows: (i) options to purchase 596,537 shares of Common Stock at prices ranging from \$1.22 to \$2.03 with expiration dates ranging up to October 8, 2012 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.

*C. Pro Forma Net Loss Information:*

The Company applies Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, in accounting for its 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,	
	2004	2003	2004	2003
As reported net loss	\$ (11,370,000)	\$ (2,966,000)	\$ (23,394,000)	\$ (8,397,000)
Adjustment to compensation expense for stock-based awards	\$ (306,000)	\$ (248,000)	\$ (608,000)	\$ (518,000)
Pro forma net loss	\$ (11,676,000)	\$ (3,214,000)	\$ (24,002,000)	\$ (8,915,000)
As reported net loss per common share, basic and diluted	\$ (0.24)	\$ (0.06)	\$ (0.49)	\$ (0.18)
Pro forma net loss per common share, basic and diluted	\$ (0.25)	\$ (0.07)	\$ (0.51)	\$ (0.19)

*D. Comprehensive Loss*

Comprehensive loss for the three and six month periods ended March 31, 2004 and 2003, respectively, is as follows:

	Three Months Ended		Six Months Ended	
	March 31,		March 31,	
	2004	2003	2004	2003
Net loss	\$ (11,370,000)	\$ (2,966,000)	\$ (23,394,000)	\$ (8,397,000)

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Change in unrealized net gain or (loss) on investments	70,000	(26,000)	40,000	(32,000)
Comprehensive loss	\$ (11,300,000)	\$ (2,992,000)	\$ (23,354,000)	\$ (8,429,000)

### E. Agreements

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 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.

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.

---

**Table of Contents**

*F. Subsequent Event*

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), under review 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 due no later than 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 will retain a specialty sales force, subsidized by Pliva, which will 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.

*G. Recent Accounting Pronouncement*

In January 2003, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, ( FIN 46 ). FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity ( VIE ), the assets, liabilities and results of activities of the VIE should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. The Company does not have any financial interests in VIE s created after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 requires its provisions, as amended by FIN 46R which was issued by the FASB in December 2003, be adopted by the Company in the second quarter of fiscal 2004. The 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.

---

**Table of Contents**

*H. 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 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 March 31, 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 March 31, 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 March 31, 2004, we have an accrued liability of approximately \$700,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly 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



## **Table of Contents**

Factors in the Company's Post-Effective Amendment No. 3 to Registration Statement on Form S-3 as filed with the SEC on March 31, 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, including the co-promotion licensing agreement related to SANCTURA; dependence on third parties for manufacturing and marketing; competition; need for additional funds and corporate partners, including for the development and commercialization 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 multiple compounds in late-stage clinical development. We currently have rights to six compounds in development: SANCTURA for overactive bladder, 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, aminocandin for treatment of systemic fungal infections and citicoline for ischemic stroke.

## **Recent Product Developments**

### SANCTURA

Effective April 6, 2004, the Company entered into the Pliva Agreement for the U.S. commercialization of SANCTURA under review by the 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 due no later than 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, which may be adjusted for settlement of the aggregate promotion and advertising costs incurred. 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.



## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 will retain a specialty sales force, subsidized by Pliva, which will 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 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 Pliva Agreement is filed as an exhibit to our Form 8-K dated April 7, 2004.

We expect to record revenue pursuant to the Pliva Agreement as follows: (i) the initial payment will be 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

## **Table of Contents**

on net sales of SANCTURA and reimbursement of promotion and advertising expenses incurred by us during the co-promotion period will be reflected as revenue, net of our share of the promotion and advertising expenses incurred by Pliva, (iii) 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 (iv) sales of SANCTURA to Pliva will be reflected as revenue upon shipment.

We submitted the New Drug Application ( NDA ) for SANCTURA for overactive bladder on April 28, 2003. Pursuant to the NDA, the SANCTURA finished product will be manufactured by our licensor, Madaus AG ( Madaus ), at their manufacturing facility in Germany. We continue to work with Madaus to produce launch quantities of SANCTURA.

We submitted a second study to assess the effect of SANCTURA on the QT interval of cardiac muscle contractility in February, 2004. Although a prior QT study, completed in 2001 and designed with the current standard at that time, demonstrated no effect of SANCTURA on the QT interval, we decided to perform a second QT study based on a new standard recommended by the FDA for all drugs in the pharmacological class to which SANCTURA belongs, as well as for most new drugs. Our second trial also concluded that SANCTURA has no significant effect on the QT interval. As a result of the submission of our new QT study, we received a letter on February 12, 2004, from the FDA establishing a 90-day extension to the original Prescription Drug User Fee Act (PDUFA) action date of February 27, 2004, moving that date to May 28, 2004.

We have also recently completed a successful trial designed to explore further certain attributes of SANCTURA. The 12-week, placebo-controlled trial enrolled 658 patients at 52 sites in the U.S. Preliminary results show that the trial met all of its primary and secondary endpoints with a high degree of statistical significance, including a reduction in both micturitions (urinations) and urinary incontinence episodes among patients treated with SANCTURA versus placebo. In particular, the study confirmed a rapid onset of action within one week of therapy and a significant reduction in urge severity. The most frequent side effects seen in the trial were the common anti-cholinergic side effects of dry mouth and constipation, with results consistent with our previous studies. We hope to use these findings in discussions with the FDA to support proposed statements in the product label which may help reinforce SANCTURA's position in the marketplace. We also intend to submit the results of the study for presentation in scientific forums and publication in peer-reviewed journals.

### **Aminocandin**

In February 2004, we initiated a Phase I clinical trial with aminocandin to test the safety and tolerability of escalating single doses of aminocandin administered in healthy volunteers. Results of the trial are expected in the second half of 2004.

### **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.

## **Significant Judgments and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are constantly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

*Insurance Claim Receivable*

As of March 31, 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

---

## **Table of Contents**

( 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, 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.

## **Results of Operations**

Our net loss increased \$8,404,000 to \$(11,370,000), or \$(0.24) per share, basic, in the second quarter of fiscal 2004 from \$(2,966,000), or \$(0.06) per share, basic, in the second quarter of fiscal 2003 and increased \$14,997,000 to \$(23,394,000) in the six month period ended March 31, 2004 from \$(8,397,000) in the six month period ended March 31, 2003. These increased net losses are primarily the result of our continuing development and pre-marketing activities related to SANCTURA.

Total revenues decreased \$1,995,000, or 69%, to \$876,000 in the three month period ended March 31, 2004 from \$2,871,000 in the three month period ended March 31, 2003 and decreased \$1,890,000, or 51%, to \$1,803,000 in the six month period ended March 31, 2004 from \$3,693,000 for the six month period ended March 31, 2003. These decreases are primarily the result of contract revenue and accelerated sales milestones recognized as royalty revenue in the fiscal 2003 periods from the renegotiated agreement with Eli Lilly and Company ( Lilly ) for Sarafem. Royalty revenue in the three and six month periods ended March 31, 2004 and 2003 includes royalties received from Lilly for sales of Sarafem and the six month period ended March 31, 2003 includes \$2,184,000 of accelerated sales milestones which were one-time payments and do not recur. Contract and license fee revenue decreased \$672,000, or 80%, to \$164,000 in the six month period ended March 31, 2004 from \$836,000 in the six month period ended March 31, 2003 primarily due to a \$777,000 initial payment received in fiscal 2003 from Lilly related to the renegotiated agreement with Lilly for Sarafem.

Cost of revenues in the three and six month periods ended March 31, 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 six month periods as a result decreased revenue from Sarafem as described above.

Research and development expense increased \$1,902,000, or 59%, to \$5,142,000 in the three month period ended March 31, 2004 from \$3,240,000 in the three month period ended March 31, 2003 and increased \$5,679,000, or 81%, to \$12,696,000 in the six month period ended March 31, 2004 from \$7,017,000 in the six month period ended March 31, 2003. These increases are primarily related to SANCTURA. SANCTURA-related research and development expenses in the three and six month periods ended March 31, 2004 include clinical trial costs, costs related to the development of extended release formulations of SANCTURA and other development costs. Additionally, fiscal 2004 research and development expenses include costs related to the development of IP 751 and aminocandin. We expect to continue to incur costs related to SANCTURA for the development of extended release formulations and other development.

Marketing, general and administrative expense increased \$3,622,000, or 168%, to \$5,782,000 in the three month period ended March 31, 2004 from \$2,160,000 in the three month period ended March 31, 2003 and increased \$5,181,000, or 112%, to \$9,798,000 in the six month period ended March 31, 2004 from \$4,617,000 in the six month period ended March 31, 2003. These increases are primarily due to increased pre-marketing activities related to SANCTURA. We are continuing to expend substantial amounts on pre-marketing activities related to SANCTURA.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Investment income increased \$21,000, or 13%, to \$180,000 in the three month period ended March 31, 2004 from \$159,000 in the three month period ended March 31, 2003 and increased \$52,000, or 15%, to \$402,000 in the six month period ended March 31, 2004 from \$350,000 in the six month period ended March 31, 2004. While average invested balances are higher, market interest rates have substantially decreased from the fiscal 2003 periods resulting in a modest increase in investment income.

Interest expense of \$1,293,000 and \$2,585,000 in the three and six month periods ended March 31, 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.

If SANCTURA is approved for marketing by the FDA, we will significantly increase our costs and expenses by hiring a sales force of approximately 280 representatives and incurring significantly increased shared promotion and advertising costs with Pliva. We have commenced building our organizational infrastructure to meet the demands of creating and supporting a sales force to promote SANCTURA by hiring and recruiting employees for corporate support and sales functions. We expect to

## **Table of Contents**

record increased revenue in the second half of fiscal 2004 due to the amortization into revenue of the initial \$30 million payment received from Pliva. The \$120 million due no later than FDA approval of SANCTURA twice daily, if received, will also be amortized into revenue as earned. We expect to report losses from our current consolidated operations for fiscal 2004; if SANCTURA is approved for marketing by the FDA, we expect such losses would be increased due primarily to significantly increased sales and marketing costs.

## **Liquidity and Capital Resources**

### Cash, Cash Equivalents and Marketable Securities

At March 31, 2004, we had consolidated cash, cash equivalents and marketable securities of \$57,636,000 compared to \$84,087,000 at September 30, 2003. This decrease of \$26,451,000, including a decrease of \$15,943,000 in the three month period ended March 31, 2004, resulted primarily from \$28,032,000 of cash used by operating activities offset by \$1,591,000 of net proceeds from the issuance of common stock upon the exercise of stock options.

In April 2004, we received the initial \$30 million payment from Pliva. In addition, pursuant to the Pliva Agreement, a \$120 million payment will become due no later than FDA approval of SANCTURA twice daily. Although we are continuing to invest substantial amounts in the ongoing development and pre-commercialization activities related to SANCTURA, we believe that the amounts 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 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, 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 under which we anticipate Madaus will manufacture SANCTURA for commercial use provided that it can deliver acceptable product to satisfy U.S. regulatory and market requirements. In order to manufacture the product for sale in the United States, Madaus' manufacturing facility must comply with cGMP. Failure to meet cGMP requirements in a timely manner could cause a material delay in FDA approval, if any, and commercialization of SANCTURA. While we may seek a second source for SANCTURA if

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Madaus is unable to meet all regulatory requirements or provide the necessary quantities of SANCTURA in a timely manner, this could also cause a material delay in FDA approval, if any, and commercialization of SANCTURA.

Total research and development expenses incurred by us through March 31, 2004 on the major compounds currently being developed, including allocation of corporate general and administrative expenses, are approximately as follows: \$62,600,000 for SANCTURA, \$18,500,000 for pagoclone, \$82,500,000 for citicoline, \$10,100,000 for PRO 2000, \$2,100,000 for aminocandin and \$2,400,000 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

## **Table of Contents**

regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from March 31, 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 pegoclone. Pursuant to our new agreement with Ferrer regarding citicoline, Ferrer is responsible for all future costs for the development of citicoline. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to the uncertainty of the number of required trials and size of such trials and the duration of development. We are unable to estimate the date of development completion for citicoline because Ferrer is now responsible for its development. We are unable to estimate the date of development completion for pegoclone due to the scope complexity and cost of the type of clinical trials necessary which may require the financial assistance of a partner to complete. Actual costs and time to complete any of our products may differ significantly from the estimates.

### Analysis of Cash Flows

Cash used in operating activities for the six month period ended March 31, 2004 of \$28,032,000 consisted primarily of the net loss of \$23,394,000 and a \$3,178,000 increase in prepaid and other assets due primarily to the \$2,000,000 deposit paid to Madaus (see Commitments ) and other SANCTURA-related marketing and advertising. We paid \$2,238,000 of interest due on our convertible notes in January 2004 and will make a similar payment in July 2004.

Net cash from investing activities of \$16,087,000 is primarily due to net maturities and sales 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 \$1,591,000 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.

### 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 a potential launch of the product. The current value of this purchase order is approximately \$7,500,000, based upon recent exchange rates. In March 2004, we paid \$2,000,000 to Madaus as a deposit on this order. If SANCTURA is approved for marketing by the FDA and we launch SANCTURA in the United States, we will be 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.

### Other

### Recent Accounting Pronouncement



## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 VIEs 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.

### *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

## **Table of Contents**

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 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 March 31, 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 March 31, 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 March 31, 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.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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.

---

**Table of Contents**

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, 2004. At the meeting (i) all seven director nominees were elected; (ii) the Company's 2004 Equity Incentive Plan was approved and (iii) the appointment of PricewaterhouseCoopers LLP as the Company's independent auditors was ratified.

- (i) The following Directors were elected for a one-year term by the votes indicated: Glenn L. Cooper, M.D., 41,874,109 for, 324,147 against; Harry J. Gray, 41,562,716 for, 635,540 against; Stephen C. McCluski, 41,386,714 for, 811,542 against; Cheryl P. Morley, 41,678,985 for, 519,271 against; Malcolm Morville, Ph.D., 41,508,316 for, 689,940 against; Lee J. Schroeder, 41,742,885 for, 455,371 against; and David B. Sharrock, 39,509,175 for, 2,689,081 against.
- (ii) The Company's 2004 Equity Incentive Plan was approved by a vote of 17,374,058 for, 2,436,889 against, 208,935 abstaining, and 22,800,596 non-votes.
- (iii) The appointment of PricewaterhouseCoopers LLP was ratified by a vote of 42,379,682 for, 389,533 against, 51,262 abstaining, and 1 non-vote.



**Table of Contents**

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

(a) Exhibits

- 10.136 Agreement by and between the Company and Ferrer Internacional S.A. dated January 22, 2004 (1)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer

- 
- (1) Confidential Treatment requested for a portion of this Exhibit

(b) Reports on Form 8-K

On February 18, 2004, the Company filed a current report on Form 8-K reporting that on February 13, 2004, the Company issued a press release announcing its results for the quarterly period ended December 31, 2003.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INDEVUS PHARMACEUTICALS, INC

Date: May 12, 2004

By: /s/ Glenn L. Cooper

---

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

Date: May 12, 2004

By: /s/ Michael W. Rogers

---

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

Date: May 12, 2004

By: /s/ Dale Ritter

---

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