

INDEVUS PHARMACEUTICALS INC

Form 10-Q

February 09, 2006

[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 December 31, 2005,

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

04-3047911
(I.R.S. Employer

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

incorporation or organization)

Identification Number)

33 Hayden Avenue

Lexington, Massachusetts
(Address of principal executive offices)

02421-7971
(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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes ☐ No ☒

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

Class:
Common Stock \$.001 par value

Outstanding at February 8, 2006
47,176,248 shares

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

INDEX TO FORM 10-Q

	PAGE
<hr/>	
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
<u>Consolidated Balance Sheets as of December 31, 2005 and September 30, 2005</u>	3
<u>Consolidated Statements of Operations for the Three Months ended December 31, 2005 and 2004</u>	4
<u>Consolidated Statements of Cash Flows for the Three Months ended December 31, 2005 and 2004</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>	13
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	19
Item 4. <u>Controls and Procedures</u>	20
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	20
Item 6. <u>Exhibits</u>	21
<u>SIGNATURES</u>	22

Table of Contents**INDEVUS PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)****(Amounts in thousands except share data)**

	December 31, 2005	September 30, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 76,821	\$ 85,098
Marketable securities	12,379	16,119
Accounts receivable	1,798	2,537
Inventories	958	971
Prepaid and other current assets	2,594	2,516
	<hr/>	<hr/>
Total current assets	94,550	107,241
Property and equipment, net	1,017	1,103
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	1,678	1,843
Other assets	1,065	1,086
	<hr/>	<hr/>
Total assets	\$ 99,568	\$ 112,531
	<hr/>	<hr/>
LIABILITIES		
Current liabilities		
Accounts payable	\$ 2,671	\$ 2,297
Accrued expenses	11,201	9,910
Accrued interest	2,075	950
Deferred revenue	13,417	14,851
	<hr/>	<hr/>
Total current liabilities	29,364	28,008
Convertible notes	72,000	72,000
Deferred revenue	124,103	127,457
Other	162	202
Minority interest	6	6
	<hr/>	<hr/>
STOCKHOLDERS DEFICIT		
Convertible preferred stock \$.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding (liquidation preference December 31, 2005 \$3,026)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference December 31, 2005 \$502)	500	500
Common stock, \$.001 par value 120,000,000 shares authorized; 47,825,896 shares issued at December 31, and September 30, 2005	48	48
Additional paid-in capital	308,418	307,435
Accumulated deficit	(434,051)	(422,121)
Accumulated other comprehensive loss	(1)	(4)
Treasury stock, at cost, 657,607 and 660,607 shares at December 31 and September 30, 2005, respectively	(3,981)	(4,000)
	<hr/>	<hr/>
Total stockholders deficit	(126,067)	(115,142)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Total liabilities and stockholders' deficit	\$ 99,568	\$ 112,531
---	-----------	------------

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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For the three months ended December 31, 2005 and 2004

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended December 31,	
	2005	2004
Revenues:		
Product revenue	\$ 3,429	\$ 3,467
Contract and license fees	5,545	2,296
Total revenues	8,974	5,763
Costs and expenses:		
Cost of product revenue	1,870	2,480
Research and development	10,320	5,878
Marketing, general and administrative	8,308	17,481
Total costs and expenses	20,498	25,839
Loss from operations	(11,524)	(20,076)
Investment income	886	674
Interest expense	(1,292)	(1,292)
Loss before income taxes	(11,930)	(20,694)
Provision for income taxes		(455)
Net loss	\$ (11,930)	\$ (21,149)
Net loss per common share, basic and diluted	\$ (0.25)	\$ (0.44)
Weighted average common shares outstanding:		
Basic and diluted	47,166	47,826

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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended December 31, 2005 and 2004

(Unaudited)

(Amounts in thousands)

	For the three months ended December 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	\$ (11,930)	\$ (21,149)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	129	80
Amortization of convertible note issuance costs	165	165
Noncash compensation	1,007	
Changes in assets and liabilities:		
Accounts receivable	739	4,404
Inventories	13	(1,723)
Prepaid and other assets	(57)	(824)
Accounts payable	374	(1,789)
Deferred revenue	(4,788)	(3,125)
Accrued expenses and other liabilities	2,367	855
Net cash used in operating activities	(11,981)	(23,106)
Cash flows from investing activities:		
Purchases of property and equipment	(43)	(232)
Proceeds from maturities and sales of marketable securities	3,743	2,314
Net cash provided by investing activities	3,700	2,082
Cash flows from financing activities:		
Net proceeds from issuance of treasury stock	4	478
Net cash provided by financing activities	4	478
Net change in cash and cash equivalents	(8,277)	(20,546)
Cash and cash equivalents at beginning of period	85,098	103,099
Cash and cash equivalents at end of period	\$ 76,821	\$ 82,553

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, 2005.

The Company concluded that it was appropriate to classify its investments in auction rate securities as short-term available-for-sale investments commencing with the preparation of its consolidated financial statements for the year ended September 30, 2005. Previously, such investments were classified as cash and cash equivalents. Accordingly, the Company has revised the classification to exclude from cash and cash equivalents \$24.0 million of auction rate securities at September 30, 2004 and December 31, 2004, respectively, and to include such amounts as short-term available-for-sale investments. There were no purchases or maturities or sales of auction rate securities during the three month period ended December 31, 2004 therefore the reclassification had no effect on cash flows from investing activities in the three month period ended December 31, 2004. This revision in classification does not affect previously reported cash flows from operations or from financing activities.

Certain prior year amounts have been reclassified to conform to fiscal 2006 classifications.

Indevus is a biopharmaceutical company engaged in the acquisition, development and commercialization of products targeting certain medical specialty areas, including urology, gynecology, and men's health. The Company markets SANCTURA® for overactive bladder and, on January 9, 2006, it commenced marketing DELATESTRYL® for the treatment of male hypogonadism (see Note K).

B. Revenue Recognition:

Product revenue consists of revenues from sales of products, commissions and royalties, and reimbursements for royalties owed by the Company to Madaus GmbH (Madaus) pursuant to the SANCTURA Agreement (see Note G). Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities. In addition, for the three month period ended December 31, 2004, contract and license fee revenue also included reimbursements from our SANCTURA marketing partner for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to its SANCTURA marketing partner for the Company's share of SANCTURA promotion and advertising costs incurred by the Company's SANCTURA marketing partner.

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. If 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, the Company recognizes such royalty revenue in the subsequent accounting period when it receives the royalty report 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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued

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 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.

Under the SANCTURA 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 SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force (EITF) Issue Number 00-21, Accounting Revenue Arrangements with Multiple Deliverables (EITF 00-21). Pursuant to EITF 00-21, in multiple element arrangements where the Company has continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its 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, 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 SANCTURA Agreement, the Company and its SANCTURA marketing partner were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from the Company's marketing partner for their share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by its SANCTURA marketing partner, reimbursements to its SANCTURA marketing partner 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

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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:

	December 31, 2005	September 30, 2005
Raw materials	\$ 958,000	\$ 971,000
Finished goods		
	\$ 958,000	\$ 971,000

Inventories consist solely of SANCTURA. Raw materials consist of tablets of SANCTURA in bulk form purchased from the Company's supplier, Madaus.

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued

D. Basic and Diluted Loss per Common Share

During the three month period ended December 31, 2005, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible 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 because the effect of their conversion would be antidilutive and (ii) options to purchase 6,573,000 shares of Common Stock at prices ranging from \$4.06 to \$20.13 with expiration dates ranging up to November 29, 2015 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended December 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 5,410,000 shares of Common Stock at prices ranging from \$1.22 to \$3.80 with expiration dates ranging up to October 25, 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 with an expiration date of July 17, 2006.

During the three month period ended December 31, 2004, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible 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 because the effect of their conversion would be antidilutive and (ii) options to purchase 1,306,000 shares of Common Stock at prices ranging from \$6.68 to \$20.13 with expiration dates ranging up to September 28, 2014 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended December 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 \$6.61 with expiration dates ranging up to August 17, 2014; (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 with an expiration date of July 17, 2006.

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.

Table of Contents**INDEVUS PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued***E. Accounting for Stock-Based Compensation*

The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R Accounting for Stock-Based Compensation (SFAS 123R) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. Stock-based employee compensation expense was \$707,000 before tax for the three month period ended December 31, 2005. Previously the Company had followed Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

Additionally, the Board of Directors adopted a provision to the Company's stock option plans relating to the retirement of employees and directors who are also reporting persons pursuant to Section 16 of the Securities Exchange Act of 1934. This provision stipulates that awards to such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were vested at the date of retirement. Pursuant to SFAS 123R, the Company is required to record the value of this modification to existing stock options. In the three month period ended December 31, 2005, the Company recorded \$300,000 of noncash compensation expense related to this modification.

The Company recognized the full impact of its share-based payment plans, including the impact of the charge related to the modification explained above, in the consolidated statement of operations for the three month period ended December 31, 2005 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets as such costs that qualified for capitalization were not material. The Company allocated these noncash expenses in the three month period ended December 31, 2005 as follows: \$148,000 to research and development and \$859,000 to marketing, general and administrative expense.

The Company had previously adopted the provisions of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, through disclosure only. The following table illustrates the effect on net income and earnings per share for the three month period ended December 31, 2004 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards.

Net loss as reported	\$ (21,149,000)
Add: Employee compensation expense for share options included in reported net income, net of income taxes	
Less: Total employee compensation expense for share options determined under the fair value method, net of income taxes	(665,000)
Pro forma net loss	\$ (21,814,000)
Net loss per share:	
Basic and diluted as reported	\$ (0.44)
Basic and diluted pro forma	\$ (0.46)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model.

The Company's expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock option grants issued during the three-month period ended December 31, 2005, the Company used a weighted-average expected stock-price volatility of 63%.

Table of Contents**INDEVUS PHARMACEUTICALS, INC.****NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued**

The Company determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three month period ended December 31, 2005, the Company used a weighted average expected option life assumption of 6.25 years.

The risk-free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

	Three Months Ended December 31,	
	2005	2004
Option life	6.25 years	4.0 years
Risk-free interest rate	4.25%	4.0%
Stock volatility	63%	60%
Dividend rate	0%	0%

As of December 31, 2005, there remained approximately \$5,800,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.4 years.

Presented below is the Company's stock option activity:

	Three Months Ended			
	December 31, 2005		December 31, 2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	11,848,295	\$ 4.49	10,931,792	\$ 4.57
Granted	182,000	\$ 2.89	198,000	\$ 6.69
Exercised	(3,000)	\$ 1.45	(186,790)	\$ 2.56
Cancelled	(27,605)	\$ 7.37	(14,375)	\$ 7.38
Outstanding at end of period	11,999,690	\$ 4.46	10,928,627	\$ 4.64
Options exercisable at end of period	9,258,995		8,501,053	
Weighted average fair value of options granted		\$ 1.80		\$ 3.36

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

At December 31, 2005, stock options were outstanding and exercisable as follows:

Range of Exercise Price	Outstanding			Exercisable	
	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
\$1.22-\$ 2.38	3,046,044	4.3 years	\$ 2.26	3,035,210	\$ 2.26
\$2.45-\$ 4.06	3,086,917	6.5 years	\$ 3.48	1,575,086	\$ 3.76
\$4.11-\$ 6.19	4,268,167	4.2 years	\$ 5.63	3,777,188	\$ 5.61
\$6.21-\$20.13	1,598,562	7.6 years	\$ 7.40	871,511	\$ 7.70
\$1.22-\$20.13	11,999,690	5.3 years	\$ 4.46	9,258,995	\$ 4.40

The aggregate intrinsic value of outstanding options as of December 31, 2005 was \$16.5 million, of which \$13.1 million related to exercisable options. The intrinsic value of options exercised during the period was \$9,000. The intrinsic value of options vested during the period was \$75,000.

F. Comprehensive Loss

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

	Three months ended December 31,	
	2005	2004
Net loss	\$ (11,930,000)	\$ (21,149,000)
Change in unrealized net gain or (loss) on investments	3,000	(69,000)
Comprehensive loss	\$ (11,927,000)	\$ (21,218,000)

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued

G. SANCTURA

In April 2004, the Company entered into a license, commercialization and supply agreement with PLIVA d.d. (PLIVA) through its specialty-branded subsidiary, Odyssey Pharmaceuticals, Inc. for the U.S. commercialization of SANCTURA for overactive bladder (the SANCTURA Agreement). In May 2005, the Company, PLIVA and Esprit Pharma Holding Company (Esprit) entered into an Amendment and Consent Agreement (the Amendment and Consent), which became effective as of July 1, 2005, pursuant to which the Company amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA's obligations under the SANCTURA Agreement.

For the six months following the approval of SANCTURA, called the co-promotion period, the Company received a commission based on net sales of SANCTURA, a portion of which funded the Company's sales force and certain advertising and promotional costs. The Company was co-promoting SANCTURA with PLIVA through a joint sales force of approximately 500 sales representatives. The Company established a sales force initially numbering approximately 280 representatives promoting SANCTURA to urology specialists, obstetricians and gynecologists, and certain primary care physicians.

The Company exercised its right to convert the SANCTURA Agreement into a royalty-bearing structure effective November 29, 2004 (the Conversion). Upon the Conversion, approximately 200 of the Company's primary care sales representatives became PLIVA employees and PLIVA became responsible for promotional, advertising and sales force-related costs. Effective upon the Conversion, the Company began receiving royalties on net sales of SANCTURA and a sales force subsidy at an annual rate of approximately \$7,700,000. Pursuant to the Amendment and Consent, the Company commenced receiving minimum annual royalties at an annual rate of \$5,625,000 and the annual sales force subsidy increased to \$8,750,000.

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 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.

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

At December 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 significantly from the amount currently accrued at December 31, 2005. To the extent amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

As of December 31, 2005, 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 has

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS - Continued

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 December 31, 2005. 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.

I. Income taxes

The provision for income taxes of \$455,000 for the three month period ended December 31, 2004 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 minimum tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

J. Recent Accounting Pronouncements

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 is a replacement of APB No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company will adopt this pronouncement beginning October 1, 2006.

K. Agreement

In December 2005, the Company entered into an agreement to acquire DELATESTRYL[®], (testosterone enanthate), an injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. (Savient) (the DELATESTRYL Agreement). The DELATESTRYL Agreement closed on January 9, 2006. Upon closing, the Company paid Savient \$5,644,000, including \$644,000 for DELATESTRYL inventory. The Company owes Savient an additional \$1,289,000 payable in two equal installments of approximately \$644,000 on the first and second anniversary of the closing. Additionally, the Company assumed Savient's previous obligation to purchase approximately \$1,100,000 of additional DELATESTRYL inventory. The Company commenced selling DELATESTRYL upon closing. Under the terms of the DELATESTRYL Agreement, the Company will pay royalties to Savient for three years following the closing of the transaction based upon the cumulative net sales of DELATESTRYL. The royalty rate will be 5% on the first \$5 million of cumulative net sales following closing increasing to 10% on cumulative net sales between \$5 million and \$10 million. The royalty rate on cumulative net sales above \$10 million will be 25%, subject to a minimum annual payment of \$300,000 following the quarter in which cumulative net sales reach \$10 million.

Table of Contents

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 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 and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (tospium chloride tablets) and SANCTURA XR (once-a-day SANCTURA); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux-related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and trends and do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company's Form 10-K for the fiscal year ended September 30, 2005. These factors include, but are not limited to: dependence on the success of SANCTURA and SANCTURA XR; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA, SANCTURA XR and NEBIDO®; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR; dependence on third parties for manufacturing, marketing and clinical trials; 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; our reliance on intellectual property and having 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, 2005. 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.

Description of the Company

We are a biopharmaceutical company engaged in the acquisition, development and commercialization of products targeting certain medical specialty areas, including urology, gynecology and men's health. We currently market SANCTURA for overactive bladder and DELATESTRYL for the treatment of male hypogonadism. The Company has multiple compounds in clinical development, including SANCTURA XR, the once-daily formulation of SANCTURA, NEBIDO for the treatment of male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually transmitted pathogens, IP 751 for interstitial cystitis, pagoclone for stuttering, and aminocandin for systemic fungal infections.

Recent Product Developments

SANCTURA XR

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

The SANCTURA XR Phase III clinical program for overactive bladder is continuing to enroll patients. We anticipate reporting results from the first of our two 600-patient trials in the middle of the calendar year. Results from the second 600-patient trial are expected to be announced by the end of the third calendar quarter. We continue to anticipate filing an NDA with the FDA by the end of calendar 2006.

NEBIDO

We recently filed an IND with the FDA for NEBIDO® for the treatment of male hypogonadism. The IND includes the European clinical data from our partner Schering AG. We are currently in the planning stages of a pharmacokinetic study to supplement the European database and intend to initiate the study upon FDA review and approval of the protocol.

DELATESTRYL

On January 9, 2006, we completed our acquisition of DELATESTRYL and paid Savient \$5,644,000, including \$644,000 for DELATESTRYL inventory. We owe Savient an additional \$1,289,000 for the DELATESTRYL inventory acquired at the closing which is payable in two equal installments of approximately \$644,000 on the first and second anniversaries of the closing. Additionally, we assumed Savient's previous obligation to purchase approximately \$1,100,000 of additional DELATESTRYL inventory. We commenced selling DELATESTRYL upon closing.

Critical Accounting Policies 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 United

Table of Contents

States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

Expected Term of the SANCTURA Agreement and Deferred Revenue

We have recorded the \$161,000,000 of initial and milestone payments received pursuant to the SANCTURA Agreement as deferred revenue and are amortizing each component into revenue using the contingency-adjusted method over the estimated remaining duration of the SANCTURA Agreement commencing on the date such payments are earned. We believe the estimated term of the SANCTURA Agreement is a significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet.

The balance of deferred revenue at December 31, 2005 is \$137,520,000. We will reevaluate our estimate of the expected term of the SANCTURA Agreement when new information is known that could affect this estimate. If we change our estimate of the duration of the SANCTURA 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.

Accounting for Stock-Based Compensation

We have several stock-based employee compensation plans. On October 1, 2005, we adopted Statement of Financial Accounting Standards No. 123R Accounting for Stock-Based Compensation (SFAS 123R) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. Stock-based employee compensation expense was \$707,000 before tax for the three months ended December 31, 2005. Previously, we had followed Accounting Principles Board Opinion No. 25,

Accounting for Stock Issued to Employees, and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

We were required to make significant estimates related to the adoption of SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources. For stock option grants issued during the three month period ended December 31, 2005, we used a weighted-average expected stock-price volatility of 63%. We also determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three month period ended December 31, 2005, the Company used a weighted-average expected option life assumption of 6.25 years.

Additionally, the Board of Directors adopted a provision to our stock option plans relating to the retirement of employees and directors who are also reporting persons pursuant to Section 16 of the Securities Exchange Act of 1934. This provision stipulates that awards to such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were vested at the date of retirement. Pursuant to SFAS 123R, we are required to record the value of this modification to existing stock options. In the

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

three month period ended December 31, 2005, the Company recorded \$300,000 of noncash compensation expense related to this modification.

We recognized the full impact of our share-based payment plans, including the impact of the charge related to the modification explained above, in the consolidated statement of income for the three month period ended December 31, 2005 under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets, as such costs that qualified for capitalization were not material. We allocated these noncash expenses in the three month period ended December 31, 2005 as follows: \$148,000 to research and development and \$859,000 to marketing, general and administrative expense. As of December 31, 2005, there remained approximately \$5,800,000 of compensation costs related to non-vested stock options to be recognized over a weighted-average period of approximately 1.4 years.

Presented below is the Company's stock option activity:

	Three Months Ended			
	December 31, 2005		December 31, 2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	11,848,295	\$ 4.49	10,931,792	\$ 4.57
Granted	182,000	\$ 2.89	198,000	\$ 6.69
Exercised	(3,000)	\$ 1.45	(186,790)	\$ 2.56
Cancelled	(27,605)	\$ 7.37	(14,375)	\$ 7.38
Outstanding at end of period	11,999,690	\$ 4.46	10,928,627	\$ 4.64
Options exercisable at end of period	9,258,995		8,501,053	
Weighted average fair value of options granted		\$ 1.80		\$ 3.36

At December 31, 2005, stock options were outstanding and exercisable as follows:

Range of Exercise Price	Outstanding			Exercisable	
	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
\$1.22-\$ 2.38	3,046,044	4.3 years	\$ 2.26	3,035,210	\$ 2.26
\$2.45-\$ 4.06	3,086,917	6.5 years	\$ 3.48	1,575,086	\$ 3.76
\$4.11-\$ 6.19	4,268,167	4.2 years	\$ 5.63	3,777,188	\$ 5.61
\$6.21-\$20.13	1,598,562	7.6 years	\$ 7.40	871,511	\$ 7.70
\$1.22-\$20.13	11,999,690	5.3 years	\$ 4.46	9,258,995	\$ 4.40

The aggregate intrinsic value of outstanding options as of December 31, 2005 was \$16.5 million, of which \$13.1 million related to exercisable options. The intrinsic value of options exercised during the period was \$9,000. The intrinsic value of options vested during the period was \$75,000.

Table of Contents

Insurance Claim Receivable

As of December 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 December 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.

Redux-Related Liabilities

At December 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 December 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.

Revenue Recognition Policy

Product revenue consists of revenues from sales of products, commissions and royalties, and reimbursements for royalties owed by us to Madaus pursuant to the SANCTURA Agreement. Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from customers, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities. In addition, for the three month period ended December 31, 2004, contract and license fee revenue also included reimbursements from our SANCTURA marketing partner for their share of SANCTURA promotion and advertising costs incurred by the Company less an amount owed by the Company to our SANCTURA marketing partner for the Company's share of SANCTURA promotion and advertising costs incurred by our SANCTURA marketing partner.

We record 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. If 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, the Company recognizes such royalty revenue in the subsequent accounting period when it receives the royalty report 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

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 the Company has no continuing performance

Table of Contents

obligations are recognized upon achievement of the related milestone. The Company records such revenue as contract and license fee revenue.

Under the SANCTURA 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 SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force (EITF) Issue Number 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, 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 SANCTURA Agreement, we and our SANCTURA marketing partner were contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by us, reimbursements from the Company's marketing partner for their share are reflected in contract and license fee revenue. For promotion and advertising costs incurred by our SANCTURA marketing partner, reimbursements to our SANCTURA marketing partner for our share were 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 \$9,219,000, or 44%, to \$(11,930,000), or \$(0.25) per share, basic, in the three month period ended December 31, 2005 from \$(21,149,000), or \$(0.44) per share, basic, in the three month period ended December 31, 2004. This decreased net loss is primarily the result of our decreased marketing activities related to SANCTURA, net of increased research and development expense and revenue related to SANCTURA and noncash charges relating to our adoption of SFAS 123R. SANCTURA marketing costs became the sole responsibility of our marketing partner on November 29, 2004 pursuant to the Conversion.

Total revenues increased \$3,211,000, or 56%, to \$8,974,000 in the three month period ended December 31, 2005 from \$5,763,000 in the three month period ended December 31, 2004 primarily due to SANCTURA-related revenues. Product revenue decreased \$38,000 to \$3,429,000 in the three month period ended December 31, 2005 from \$3,467,000 in the three month period ended December 31, 2004. An increase in royalties from SANCTURA of \$817,000 to \$1,758,000 in the three month period ended December 31, 2005 from \$940,000 in the three month period ended December 31, 2004 was substantially offset by a \$628,000 decrease in sales of SANCTURA to \$1,434,000 in the three month period ended December 31, 2005 from \$2,062,000 in the three month period ended December 31, 2004. Royalties in the three month period ended December 31, 2005 reflected the minimum royalties due pursuant to the SANCTURA Agreement. There were no minimum royalties in the three month period ended December 31, 2004. We expect royalty revenue from SANCTURA in fiscal 2006 will continue to reflect such minimum royalties. We sell SANCTURA to our marketing partner at our cost to manufacture.

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

Contract and license fee revenues relate almost entirely to the SANCTURA Agreement and increased \$3,249,000, or 142%, to \$5,545,000 in the three month period ended December 31, 2005 from \$2,296,000 in the three month period ended December 31, 2004. An increase in contract and license fee revenue of \$1,548,000 resulted from \$2,187,000 of sales force subsidy pursuant to the SANCTURA Agreement for three month period ended December 31, 2005 compared to \$640,000 for only one month of subsidy in the three month period ended December 31, 2004. The three month period ended December 31, 2004 included a \$1,482,000 reduction to contract and license fee revenue for net reimbursement due to PLIVA for SANCTURA promotion and advertising costs; the absence of a similar reimbursement in the three month period ended December 31, 2005 resulted in an increase in contract and license fee revenue. After the copromotion period ended November 29, 2004 pursuant to the Conversion, PLIVA became responsible for promotion and advertising costs. Also included in contract and license fee revenue was \$3,354,000 and \$3,125,000 from amortization of deferred revenue in the three month periods ended December 31, 2005 and 2004, respectively.

Table of Contents

Cost of product revenue decreased \$610,000, or 25%, to \$1,870,000 in the three month period ended December 31, 2005 from \$2,480,000 in the three month period ended December 31, 2004. This decrease is primarily due to a \$721,000 decrease in the cost of SANCTURA product sold to \$1,341,000 in the three month period ended December 31, 2005 from \$2,062,000 in the three month period ended December 31, 2004 and relates to the decrease in sales of SANCTURA product as described above.

Research and development expense increased \$4,442,000, or 76%, to \$10,320,000 in the three month period ended December 31, 2005 from \$5,878,000 in the three month period ended December 31, 2004. This increase is primarily due to higher external product development costs of approximately \$3,900,000 related to our Phase III clinical development program for SANCTURA XR initiated in September 2005. An increase in pagoclone external development costs of approximately \$1,000,000 related to our Phase II clinical trial for stuttering was offset by \$1,000,000 of decreased aminocandin external development costs which included a \$750,000 milestone payment in the three month period ended December 31, 2004.

Marketing, general and administrative expense decreased \$9,173,000, or 52%, to \$8,308,000 in the three month period ended December 31, 2005 from \$17,481,000 in the three month period ended December 31, 2004 and was primarily caused by a decrease in marketing expense. Marketing expenses, relating primarily to SANCTURA, decreased \$10,069,000, or 69%, to \$4,573,000 in the three month period ended December 31, 2005 from \$14,642,000 in the three month period ended December 31, 2004. This decrease in marketing expense included approximately \$5,900,000 of decreased promotion and advertising expense related to SANCTURA. As noted above, after the copromotion period ended November 29, 2004 pursuant to the Conversion, PLIVA became responsible for promotion and advertising costs. Additionally, the three month period ended December 31, 2004 included approximately \$4,500,000 for two months of expense related to approximately 200 primary care sales representatives transferred to PLIVA at the end of November 2004 pursuant to the Conversion.

General and administrative expenses increased \$896,000, or 32%, to \$3,735,000 in the three month period ended December 31, 2005 from \$2,839,000 in the three month period ended December 31, 2004. This increase is due primarily to \$859,000 of noncash option compensation expense from the adoption of SFAS 123R.

Investment income increased \$212,000, or 31%, to \$886,000 in the three month period ended December 31, 2005 from \$674,000 in the three month period ended December 31, 2004. While weighted average invested balances in the three month period ended December 31, 2005 were somewhat lower than weighted average invested balances in the three month period ended December 31, 2004, the increase in investment income is due to higher interest rates.

Interest expense of \$1,292,000 in the three month periods ended December 31, 2005 and 2004 relates to our \$72,000,000 of 6.25% Convertible Senior Notes due 2008 (the "Convertible Notes"). Annual interest expense is expected to be approximately \$5,859,000, which includes approximately \$700,000 of amortization of debt issuance costs.

The provision for income taxes of \$455,000 in the three month period ended December 31, 2004 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.

We expect to report losses from our current consolidated operations for fiscal 2006.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At December 31, 2005 we had consolidated cash, cash equivalents and marketable securities of \$89,200,000 compared to \$101,217,000 at September 30, 2005. This decrease of \$12,017,000 was primarily the result of net cash used in operating activities of \$11,981,000 (see Analysis of Cash Flows).

We are continuing to invest substantial amounts in the ongoing development and sales activities related to SANCTURA and our other product candidates. In January 2006, we paid approximately \$5.6 million to Savient related to our purchase of DELATESTRYL and will pay approximately \$2.4 million additionally for DELATESTRYL inventory. We believe we have sufficient cash for currently planned expenditures for at least the next twelve months.

We will require additional funds or corporate collaborations for the development and commercialization of our other product candidates, as well as any new businesses, products or technologies acquired or developed in the future. We have no

Table of Contents

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

On December 28, 2005, we filed a shelf registration statement on Form S-3 with the SEC. The shelf registration statement has been declared effective and will give us the option to offer and sell up to 10 million shares of our common stock from time to time and through one or more methods of distribution, subject to market conditions and our capital needs. The terms of the offerings would be established at the time of the offering. Currently, we do not have any commitments to sell shares under the registration statement. However, the registration statement has been filed in order to provide us with the flexibility, as we deem appropriate, to raise additional capital in the future.

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 XR, NEBIDO and other development efforts. We are responsible for conducting and funding the development of SANCTURA XR. We could receive approximately \$45 million in future payments contingent upon the filing and approval of an NDA for SANCTURA XR. If Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR, Esprit will not have an obligation to pay the development milestone of approximately \$35.0 million related to the FDA approval of the NDA for SANCTURA XR or the \$20.0 million long-term commercialization milestone and the U.S. rights to SANCTURA XR will revert to us.

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 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.

Total research and development expenses incurred by us through December 31, 2005 on the major compounds currently being developed or marketed, including up-front and milestone payments and allocation of corporate general and administrative expenses, are approximately as follows: \$108,000,000 for SANCTURA and SANCTURA XR, \$9,200,000 for NEBIDO, \$15,500,000 for PRO 2000, \$4,200,000 for IP 751, \$25,300,000 for pagoclone, and \$11,000,000 for aminocandin. In June 2002, we re-acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from December 31, 2005 through the preparation of an NDA for our major compounds currently being developed as follows: approximately \$15,000,000 for SANCTURA XR, \$16,000,000 for NEBIDO, \$15,000,000 for PRO 2000, approximately \$20,000,000 for IP 751, and approximately \$43,000,000 for pagoclone. We do not expect to conduct significant additional development of aminocandin without a development and marketing partner. Currently estimated research and development costs through the preparation of an NDA for aminocandin are approximately \$89,000,000. 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 in the three month period ended December 31, 2005 of \$11,981,000 consisted primarily of the net loss of \$11,930,000. The net decrease in deferred revenue of \$4,788,000 is the result of \$3,354,000 of amortization into contract and license fee revenue and \$1,434,000 recognized as product revenue for shipments of SANCTURA to our marketing partner. A source of cash of \$2,367,000 from an increase in accrued expenses and other liabilities primarily resulted from increases in accrued interest on our Convertible Notes, accrued inventory costs related primarily to purchases of bulk SANCTURA tablets from Madaus and accrued contract costs related to our research and

Table of Contents

development activities. An additional source of cash was noncash compensation expense of \$1,007,000 related to stock option expense pursuant to our adoption of SFAS 123R.

Net cash provided by investing activities of \$3,700,000 is primarily due to maturities and sales of marketable securities of \$3,743,000.

Contractual Obligations and Off-Balance Sheet Arrangements

Pursuant to the Madaus Agreement, we are committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2006 aggregating approximately \$9,700,000. If we do not satisfy this minimum purchase requirement, we would be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Pursuant to the SANCTURA Agreement, Esprit agreed to purchase the same quantities of SANCTURA and to be responsible for commercial product procurement costs, including costs to manufacture SANCTURA and the minimum supply fee.

At December 31, 2005, we had a remaining liability of \$843,000 related to the nonutilization of our prior office facility which is unoccupied.

Pursuant to certain of our in-licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. We cannot predict if or when such events will occur.

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.

Other

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 is a replacement of Accounting Principles Board Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company will adopt this pronouncement beginning October 1, 2006.

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 Convertible Notes

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible 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 \$40. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a \$1000 Note by approximately \$15. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes due to fluctuations in the market value of our Common Stock or interest rates could vary substantially from these examples.

Table of Contents

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of December 31, 2005, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2005 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. 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.

As of December 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 December 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.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2005 that have materially affected, or are 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

Table of Contents

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 6. Exhibits

(a) Exhibits

- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

INDEVUS PHARMACEUTICALS, INC.

Date: February 9, 2006

By: /s/ Glenn L. Cooper
Glenn L. Cooper, M.D., Chairman, President,

and Chief Executive Officer (Principal Executive

Officer)

Date: February 9, 2006

By: /s/ Michael W. Rogers
Michael W. Rogers, Executive Vice President,

Chief Financial Officer and Treasurer

(Principal Financial Officer)

Date: February 9, 2006

By: /s/ Dale Ritter
Dale Ritter, Senior Vice President, Finance

(Principal Accounting Officer)