

INDEVUS PHARMACEUTICALS INC

Form 10-Q

August 07, 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 June 30, 2006,**

**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)

**04-3047911**  
(I.R.S. Employer

Identification Number)

**33 Hayden Avenue**  
  
**Lexington, Massachusetts**  
(Address of principal executive offices)

**02421-7971**  
(Zip Code)

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

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 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.

	Outstanding at
Class:	August 2, 2006
Common Stock \$.001 par value	55,880,231 shares

---

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

**INDEX TO FORM 10-Q**

	<b>PAGE</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	
<u>Consolidated Balance Sheets as of June 30, 2006 and September 30, 2005</u>	1
<u>Consolidated Statements of Operations for the Three and Nine Months ended June 30, 2006 and 2005</u>	2
<u>Consolidated Statements of Cash Flows for the Nine Months ended June 30, 2006 and 2005</u>	3
<u>Notes to Unaudited Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	25
Item 4. <u>Controls and Procedures</u>	25
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	26
Item 6. <u>Exhibits</u>	27
<u>SIGNATURES</u>	28

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

	June 30,	September 30,
	2006	2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 44,325	\$ 85,098
Marketable securities	9,000	16,119
Accounts receivable, net	5,517	2,537
Inventories	7,492	971
Prepaid and other current assets	3,471	2,516
Total current assets	69,805	107,241
Property and equipment, net	876	1,103
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	1,348	1,843
Inventories	3,409	
Other assets	2,603	1,086
Total assets	\$ 79,299	\$ 112,531
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$ 8,428	\$ 2,297
Accrued expenses	10,641	9,910
Accrued interest	2,075	950
Deferred revenue	13,417	14,851
Total current liabilities	34,561	28,008
Convertible notes	72,000	72,000
Deferred revenue	117,394	127,457
Other	2,145	202
Minority interest	126	6
<b>STOCKHOLDERS DEFICIT</b>		
Convertible preferred stock \$.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding (liquidation preference June 30, 2006 \$3,038)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference June 30, 2006 \$506)	500	500
Common stock, \$.001 par value, 120,000,000 shares authorized; 47,830,231 shares issued and outstanding at June 30, 2006 and 47,825,896 shares issued at September 30, 2005	48	48
Additional paid-in capital	308,179	307,435
Accumulated deficit	(458,654)	(422,121)
Accumulated other comprehensive loss		(4)
Treasury stock, at cost, 660,607 shares at September 30, 2005		(4,000)

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

Total stockholders' deficit	(146,927)	(115,142)
Total liabilities and stockholders' deficit	\$ 79,299	\$ 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 and nine months ended June 30, 2006 and 2005****(Unaudited)****(Amounts in thousands except per share data)**

	<b>Three months ended June 30,</b>		<b>Nine months ended June 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Revenues:				
Product revenue	\$ 6,294	\$ 3,143	\$ 17,166	\$ 10,848
Contract and license fees	5,585	5,050	18,110	12,385
Total revenues	11,879	8,193	35,276	23,233
Costs and expenses:				
Cost of product revenue	4,686	1,874	12,336	7,729
Research and development	11,129	5,559	30,883	17,448
Marketing, general and administrative	8,908	9,045	26,725	34,713
Total costs and expenses	24,723	16,478	69,944	59,890
Loss from operations	(12,844)	(8,285)	(34,668)	(36,657)
Investment income	760	798	2,448	2,210
Interest expense	(1,293)	(1,293)	(3,878)	(3,878)
Minority interest and other		(9)	(435)	(183)
Loss before income taxes	(13,377)	(8,789)	(36,533)	(38,508)
Provision for income taxes		(1,000)		(2,150)
Net loss	\$ (13,377)	\$ (9,789)	\$ (36,533)	\$ (40,658)
Net loss per common share, basic and diluted	\$ (0.28)	\$ (0.21)	\$ (0.77)	\$ (0.87)
Weighted average common shares outstanding:				
Basic and diluted	47,614	46,999	47,353	46,964

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 nine months ended June 30, 2006 and 2005**

**(Unaudited)**

**(Amounts in thousands)**

	<b>For the nine months ended June 30,</b>	
	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net loss	\$ (36,533)	\$ (40,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	364	279
Amortization of convertible note issuance costs	495	495
Minority interest in net income of consolidated subsidiary	435	
Noncash consideration	(266)	
Impairment and loss on equity securities		185
Lease abandonment		1,310
Noncash stock-based compensation	3,461	75
Changes in assets and liabilities:		
Accounts receivable	(2,980)	4,931
Inventories	(9,930)	1,160
Prepaid and other assets	(2,206)	813
Accounts payable	6,131	(4,236)
Deferred revenue	(11,497)	(9,375)
Accrued expenses and other liabilities	3,458	(3,003)
Net cash used in operating activities	(49,068)	(48,024)
Cash flows from investing activities:		
Purchases of property and equipment	(137)	(983)
Proceeds from maturities and sales of marketable securities	7,119	36,152
Other	3	22
Net cash provided by investing activities	6,985	35,191
Cash flows from financing activities:		
Net proceeds from issuance of common stock and treasury stock	1,310	587
Net cash provided by financing activities	1,310	587
Net change in cash and cash equivalents	(40,773)	(12,246)
Cash and cash equivalents at beginning of period	85,098	103,099
Cash and cash equivalents at end of period	\$ 44,325	\$ 90,853

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 \$24,000,000 and \$15,000,000 of auction rate securities at September 30, 2004 and June 30, 2005, 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 nine month period ended June 30, 2005, therefore the reclassification had no effect on cash flows from investing activities in the nine month period ended June 30, 2005. 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 to treat urological, gynecological and men's health conditions. We market SANCTURA<sup>®</sup> for overactive bladder and, in January 2006, we commenced marketing DELATESTRYL<sup>®</sup> for the treatment of male hypogonadism.

*B. Revenue Recognition:*

Product revenue consists of revenues from sales of products, commissions and royalties, and reimbursements for certain royalties owed by the Company. Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from partners, 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.

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

---

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

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

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, we recognize such royalty revenue in the subsequent accounting period when we receive 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 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 for 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 SEC Staff Accounting Bulletin 104 (SAB 104), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements. In particular relating to the SANCTURA Agreement, the Company and our SANCTURA marketing partner were

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

contractually bound to share certain promotion and advertising costs relating to SANCTURA. For promotion and advertising costs incurred by the Company, reimbursements from PLIVA for our SANCTURA marketing partner's 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 the Company's share were reflected as a reduction of contract and license fee revenue.

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

*C. Inventories*

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

The components of inventory are as follows:

	<b>June 30, 2006</b>	<b>September 30, 2005</b>
Raw materials	\$ 2,097,000	\$ 971,000
Finished goods	8,804,000	
	<b>\$ 10,901,000</b>	<b>\$ 971,000</b>

Raw materials consist solely of tablets of SANCTURA in bulk form purchased from the Company's suppliers. Finished goods at June 30, 2006 consisted of \$3,396,000 of SANCTURA and \$5,408,000 of DELATESTRYL. The Company acquired the DELATESTRYL finished goods inventory pursuant to a product acquisition agreement (see Note H) and has classified \$3,409,000 of the inventory as a noncurrent asset.

*D. Basic and Diluted Loss per Common Share*

During the three month period ended June 30, 2006, 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 5,006,000 shares of Common Stock at prices ranging from \$5.18 to \$20.13 with expiration dates ranging up to June 26, 2016 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended June 30, 2006, 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 6,806,000 shares of Common Stock at prices ranging from \$1.22 to \$5.08 with expiration dates ranging up to June 28, 2016; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; (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; and (iv) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,250 contingently issuable shares.

During the three month period ended June 30, 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 8,297,000 shares of Common Stock at prices ranging from \$2.92 to \$20.13 with expiration dates ranging up to April 19, 2015 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended June 30, 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



**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

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

purchase 3,239,000 shares of Common Stock at prices ranging from \$1.22 to \$2.87 with expiration dates ranging up to June 13, 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 nine month period ended June 30, 2006, 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 5,080,000 shares of Common Stock at prices ranging from \$5.00 to \$20.13 with expiration dates ranging up to June 28, 2016 because their exercise price exceeded the average market price during the period. Additionally, during the nine month period ended June 30, 2006, 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 6,839,000 shares of Common Stock at prices ranging from \$1.22 to \$4.90 with expiration dates ranging up to May 16, 2016; (ii) Series B and C preferred stock convertible into 622,222 shares of Common Stock; (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; and (iv) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,250 contingently issuable shares.

During the nine month period ended June 30, 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 5,076,000 shares of Common Stock at prices ranging from \$5.24 to \$20.13 with expiration dates ranging up to January 24, 2015 because their exercise price exceeded the average market price during the period. Additionally, during the nine month period ended June 30, 2005, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 6,077,000 shares of Common Stock at prices ranging from \$1.22 to \$4.63 with expiration dates ranging up to January 24, 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.

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.

*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, excluding portions related to modifications and restricted stock, was \$848,000 and \$2,448,000, before tax, for the three and nine months ended June 30, 2006, respectively. 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.

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

During the three months ended December 31, 2005, the Board of Directors adopted a modification 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. In the nine months ended June 30, 2006, the Company recorded \$300,000 of noncash compensation expense related to this modification. During the nine months ended June 30, 2006, the Board of Directors approved modifications to extend the term of certain outstanding stock options and the Company recorded \$472,000 of noncash compensation expense related to these modifications. Pursuant to SFAS 123R, the Company is required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of the stock options.

During the nine month period ended June 30, 2006, the Company granted certain restricted and other unvested performance-based common stock awards to the Company's executive officers pursuant to the Company's 2004 Equity Incentive Plan. Compensation expense for these awards is recognized over the service period and is recorded as a component of marketing, general and administrative and research and development expense as appropriate. During the three and nine month periods ended June 30, 2006, \$194,000 and \$241,000 of noncash compensation expense related to these stock awards was recognized respectively.

The Company recognized the full impact of its share-based payment plans, including the impact of the charges related to the modifications and restricted stock explained above, in the consolidated statements of income for the three and nine month periods ended June 30, 2006 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. In the three month and nine month periods ended June 30, 2006, the Company recorded \$1,042,000 and \$3,461,000, respectively, of these noncash expenses. Expense recognized in connection with the adoption of FAS 123R increased the net loss for the three and nine month periods ended June 30, 2006, by \$1,042,000 and \$3,461,000, respectively, and increased loss per share, basic and diluted, \$0.02, and \$0.07, respectively. There was no impact in the three and nine month periods ended June 30, 2006 on cash flows from operations or investing and financing activities in connection with the adoption of FAS 123R. In the three month period ended June 30, 2006, the Company allocated \$206,000 and \$836,000 to research and development and marketing, general and administrative expense, respectively. In the nine month period ended June 30, 2006, the Company allocated \$558,000 and \$2,903,000 to research and development and marketing, general and administrative expense, respectively.

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 loss and loss per share for the three and nine month periods ended June 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee awards.

	<b>Three Months Ended June 30, 2005</b>	<b>Nine Months Ended June 30, 2005</b>
Net loss as reported	\$ (9,789,000)	\$ (40,658,000)
Add: Employee compensation expense for share options included in reported net loss, net of income taxes		75,000
Less: Total employee compensation expense for share options determined under the fair value method, net of income taxes	(705,000)	(2,387,000)
Pro forma net loss	\$ (10,494,000)	\$ (42,970,000)
Loss per share:		
Basic and diluted as reported	\$ (0.21)	\$ (0.87)
Basic and diluted pro forma	\$ (0.22)	\$ (0.91)

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

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.

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.

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.

Presented below are the weighted average assumptions used to value stock options granted for the periods indicated:

	Three Months Ended June 30, 2006			Nine Months Ended June 30, 2006		
	Executives	Non-executives	2005	Executives	Non-executives	2005
Option life	8 years	6.25 years	4 years	8 years	6.25 years	4 years
Risk-free interest rate	4.95%	4.85%	4.0%	4.95%	4.56%	4.0%
Stock volatility	73.0%	68.0%	60.0%	73.0%	66.0%	60.0%
Dividend rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

As of June 30, 2006, there remained approximately \$6,340,000 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:

	June 30, 2006		June 30, 2005	
	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	546,250	\$ 4.76	1,220,500	\$ 4.02
Exercised	(323,376)	\$ 3.13	(209,123)	\$ 2.51
Cancelled	(224,104)	\$ 4.84	(229,873)	\$ 6.27
Outstanding at end of period	11,847,065	\$ 4.53	11,713,296	\$ 4.51
Options exercisable at end of period	9,422,326	\$ 4.46	8,671,160	
Weighted average fair value of options granted		\$ 2.98		\$ 2.40

During the nine months ended June 30, 2006, the Company granted unvested restricted stock awards with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,250 contingently-issuable shares. Service based stock awards granted during the period have a weighted average grant date fair value of \$6.36, the closing price of the common stock on the date of the grant. Service and market based stock awards were valued using a lattice model. Service and market based stock awards granted during the period have a weighted average grant date fair value of \$4.13.

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

At June 30, 2006, there remained approximately \$2,000,000 of compensation expense related to restricted and other performance-based stock awards to be recognized as expense over approximately 2.7 years.



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

At June 30, 2006, stock options were outstanding and exercisable as follows:

Range of Exercise Price	Number	Outstanding Weighted Average	Weighted	Number	Exercisable Weighted
		Remaining	Average		Average
		Contractual Life	Exercise Price		Exercise Price
\$1.22-\$ 2.71	3,096,002	4.0 years	\$ 2.29	2,920,002	\$ 2.27
\$2.77-\$ 4.16	3,426,001	5.5 years	\$ 3.67	2,452,229	\$ 3.85
\$4.26-\$ 6.19	3,626,469	4.2 years	\$ 5.94	3,057,657	\$ 6.01
\$6.21-\$20.13	1,698,594	7.2 years	\$ 7.33	992,438	\$ 7.63
<b>\$1.22-\$20.13</b>	<b>11,874,066</b>	<b>5.0 years</b>	<b>\$ 4.53</b>	<b>9,422,326</b>	<b>\$ 4.46</b>

The aggregate intrinsic value of outstanding options as of June 30, 2006 was \$15,500,000, of which \$12,900,000 was related to exercisable options. The intrinsic value of options exercised during the three months ended June 30, 2005 was \$12,000. No options were exercised during the three months ended June 30, 2006. The intrinsic value of options exercised during the nine months ended June 30, 2006 and 2005 was \$1,037,000 and \$912,000, respectively. The intrinsic value of options vested during the three and nine months ended June 30, 2006 was \$432,000 and \$784,000, respectively. The weighted average contractual life for total options exercisable at June 30, 2006 is approximately 4.1 years.

The aggregate intrinsic value of restricted stock awards outstanding at June 30, 2006 was \$1,181,000 for awards with service based vesting criteria and from \$1,153,000 to \$1,921,000 for contingently issuable awards with service and market based vesting criteria.

**F. Comprehensive Loss**

Comprehensive loss for the three and nine months ended June 30, 2006 and 2005 is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2006	2005	2006	2005
Net loss	\$ (13,377,000)	\$ (9,789,000)	\$ (36,533,000)	\$ (40,658,000)
Change in unrealized net gain or (loss) on investments		37,000	4,000	(16,000)
<b>Comprehensive loss</b>	<b>\$ (13,377,000)</b>	<b>\$ (9,752,000)</b>	<b>\$ (36,529,000)</b>	<b>\$ (40,674,000)</b>

**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.

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

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, which funded a portion of 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

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

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

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, which increases to \$7,875,000 in the royalty year commencing July 1, 2006, and the annual sales force subsidy was increased to \$8,750,000.

In the three and nine month periods ended June 30, 2006, the Company recorded a license payment obligation as a noncurrent liability and an intangible asset which is included in other assets of \$1,500,000 in recognition of expected achievement of a contingent milestone to the Company's licensor of SANCTURA, Madaus GmbH ("Madaus"), based on cumulative net sales of SANCTURA. The intangible asset will be amortized to cost of revenue over the remaining term of the Madaus license agreement and pay the milestone when it is achieved.

***H. DELATESTRYL***

In December 2005, the Company entered into an asset purchase agreement to acquire DELATESTRYL, an injectable testosterone replacement therapy for the treatment of male hypogonadism, from Savient Pharmaceuticals, Inc. ("Savient") (the "DELATESTRYL Agreement"). On January 9, 2006, the Company completed the acquisition of DELATESTRYL for a total purchase price of \$6,821,000 and accounted for the transaction as the purchase of an asset. Upon closing, the Company paid Savient \$5,644,000 and as of June 30, 2006, the Company owes Savient an additional \$1,289,000 which is payable in two 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 \$5,000,000 of cumulative net sales following closing, increasing to 10% on cumulative net sales between \$5,000,000 and \$10,000,000. The royalty rate on cumulative net sales above \$10,000,000 will be 25%, subject to a minimum annual payment of \$200,000 following the quarter in which cumulative net sales reach \$10,000,000. Additionally, until March 2007, the Company is obligated to pay a Savient licensor 6% of net sales.

***I. 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

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

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

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.

At June 30, 2006, 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 June 30, 2006. 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 June 30, 2006, 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 recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$1,258,000 reflected as a noncurrent insurance claim receivable at June 30, 2006. 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.

*J. Income taxes*

The provision for income taxes of \$1,000,000 and \$2,150,000 for the three and nine month period ended June 30, 2005, respectively 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.

*K. Agreement*

In the nine month period ended June 30, 2006, CPEC LLC, our 65% owned subsidiary, amended its bucindolol license agreement to ARCA Discovery, Inc. resulting in \$1,266,000 of contract and license fee revenue, \$1,000,000 of which was received in cash.

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

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

*L. Subsequent Event*

On July 3, 2006, the Company completed an underwritten public offering of common stock announced on June 28, 2006. The Company issued 8,050,000 shares including 1,050,000 shares to cover underwriter over allotments, at a price to the public of \$4.65 per share. Net proceeds after underwriting commissions and expenses was approximately \$34,800,000. This offering of common stock was made pursuant to an effective shelf registration statement filed with the SEC on December 28, 2005.

*M. Recent Accounting Pronouncements*

In May 2005, the Financial Accounting Standards Board ( FASB ) issued SFAS 154, Accounting Changes and Error Corrections ( SFAS 154 ). SFAS 154 is a replacement of APB No. 20 and FASB Statement No. 3. SFAS 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 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 154. SFAS 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.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertain Tax Provisions, an Interpretation of SFAS Statement 109 ( FIN 48 ). FIN 48 clarifies the accounting for uncertain tax positions as described in SFAS No. 109, Accounting for Income Taxes, and requires a company to recognize, in its financial statements, the impact of a tax position only if that position is more likely than not of being sustained on an audit basis solely on the technical merit of the position. In addition, FIN 48 requires qualitative and quantitative disclosures including a discussion of reasonably possible changes that might occur in the recognized tax benefits over the next twelve months as well as a roll-forward of all unrecognized tax benefits. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company intends to adopt FIN 48 beginning October 2007 and is currently evaluating the impact FIN 48 might have on its consolidated results of operations and financial condition.

*N. Facilities Lease*

In June 2005, the Company occupied its new corporate headquarters and ceased using its former facilities prior to the April 2007 expiration of the lease period for such facilities. As a result, the Company recorded a charge of approximately \$1,310,000 in the three and nine month periods ended June 30, 2005 related to the non-utilization of its former facilities. The charge represented the Company's best estimate of fair value of its ongoing liability determined by comparing future lease payment obligations, net of potential sub-lease rental, and related costs in accordance with Statement of Financial Accounting Standard No. 146, Accounting for Costs Associated with Exit or Disposal Activities ( SFAS 146 ). During the nine months ended June 30, 2006, the Company settled the remaining lease obligations relating to its former facility for a payment of \$500,000 and reflected a credit of approximately \$300,000 in marketing, general, and administrative expense related to the extinguishment of the remaining accrued liability.

*O. Other*

Accrued expenses at June 30, 2006 and September 30, 2005 includes clinical and sponsored research charges of \$3,033,000 and \$3,020,000 and compensation related costs of \$3,178,000 and \$2,547,000, respectively. Property and equipment at June 30, 2006 and September 30, 2005 are shown net of accumulated depreciation of \$1,489,000 and \$1,125,000, respectively.

## **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® (trospium 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 our 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.

### **Our Business**

We are a biopharmaceutical company engaged in the acquisition, development and commercialization of products to treat urological, gynecological and men's health conditions. We currently co-promote SANCTURA® for overactive bladder, or OAB, and market DELATESTRYL® to treat male hypogonadism and we have six compounds in clinical development. Our compounds in clinical development include 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 premature ejaculation, and aminocandin for systemic fungal infections.

### **Recent Product Developments**

#### **SANCTURA XR**

We announced positive data from our first Phase III clinical trial for SANCTURA XR in June 2006 and our second Phase III clinical trial for SANCTURA XR in July 2006. The data from both trials showed that

## **Table of Contents**

SANCTURA XR met its primary endpoints, reduction in frequency of urination (toilet voids) and reduction in number of urge incontinence episodes. The trials also achieved all of their key secondary endpoints, including an increase in volume voided per void and a reduction in the severity of urgency, a defining symptom of OAB. In addition, the drug was well tolerated and had a low incidence of dry mouth, which is a common side effect in patients treated for OAB. Our first trial enrolled approximately 600 patients and our second trial enrolled approximately 560 patients. We continue to anticipate filing a New Drug Application ( NDA ) with the U.S. Food and Drug Administration ( FDA ) by the end of calendar 2006.

### **NEBIDO**

In March 2006, the FDA accepted our Investigational New Drug Application ( IND ) for NEBIDO<sup>®</sup> to treat male hypogonadism. The IND includes the European clinical data previously generated by our partner, Schering AG. We completed enrollment of our pharmacokinetic study to supplement the European data in June 2006. The primary endpoint will assess the average serum testosterone levels (Cavg) at steady state, after the fourth injection, measured in hypogonadal men receiving NEBIDO via intramuscular injection every 12 weeks. Assuming positive results, we anticipate submitting an NDA in the second quarter of calendar 2007.

### **PAGOCLONE**

In May 2006, we announced data from our Phase II clinical trial for pagoclone in persistent developmental stuttering. In this trial, pagoclone produced a statistically significant benefit in multiple primary and secondary endpoints compared to placebo and was superior to placebo on virtually all other primary and secondary endpoints. Pagoclone was also well tolerated and not associated with any serious adverse events. There were a total of 132 patients randomized in the trial. We plan to meet with the FDA to discuss the findings and our plans for further clinical development of pagoclone for stuttering.

In March 2006, we filed a New Patent Application with the U.S. Patent and Trademark Office directed towards the use of pagoclone as a treatment for premature ejaculation. The patent filing is based on evidence contained in our existing clinical databases that pagoclone may benefit men with this problem. In June 2006, we initiated a Phase II proof of concept trial for pagoclone in premature ejaculation. This trial is designed to evaluate the efficacy of various doses of pagoclone versus placebo in delaying the ejaculatory response in male patients with primary premature ejaculation. The trial is expected to enroll approximately 100 patients at multiple sites in the United States. Patients will be evaluated for a total of 9 weeks including a 4 week screening phase and a 5 week treatment phase. We anticipate announcing results of the trial in early calendar 2007.

### **DELATESTRYL**

In January 2006, we acquired DELATESTRYL, an injectable testosterone product that treats male hypogonadism, from Savient. We market DELATESTRYL to endocrinologists and urologists.

## **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 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.

## **Table of Contents**

### *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 June 30, 2006 is \$130,811,000. 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. The fair value of options at grant date was estimated using the Black-Scholes option-pricing model. Stock-based employee compensation expense, excluding portions related to modifications and restricted stock which are explained below, was \$848,000 and \$2,448,000, before tax, for the three and nine month periods ended June 30, 2006, respectively. 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 to non-executives during the three and nine month periods ended June 30, 2006, we used a weighted-average expected stock-price volatility of 67% and 65%, respectively. For stock option grants to executives during the three and nine month periods ended June 30, 2006, we used a weighted average expected stock-price volatility of 73%. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three and nine month periods ended June 30, 2006, we used a weighted-average expected option life assumption of 6.25 years for non-executives and 8.0 years for executives.

Additionally, during the nine months ended June 30, 2006 the Board of Directors adopted a modification 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 modification 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 nine month period ended June 30, 2006, we recorded \$300,000 of noncash compensation expense related to this modification. Also, during the nine months ended June 30, 2006, we amended certain provisions of outstanding stock options and recorded \$472,000 of noncash compensation expense related to these modifications.

During the nine months ended June 30, 2006, we granted 215,900 shares of restricted common stock with service-based vesting criteria and from 210,750 to 351,250 of contingently issuable shares of other unvested awards with service and market-based vesting criteria. Service-based stock awards granted during the period



## Table of Contents

have a weighted average grant date fair value of \$6.36, the closing price of the common stock on the date of the grant. Service and market based awards were valued using a lattice model. Service and market based stock awards granted during the period have a weighted average grant date fair value of \$4.13. During the three and nine month periods ended June 30, 2006, \$194,000 and \$241,000, respectively, of noncash compensation expense related to these awards was recognized. As of June 30, 2006, there remained approximately \$2,000,000 of compensation expense related to such stock awards to be recognized as expense over approximately 2.7 years.

We recognized the full impact of our share-based payment plans, including the impact of the charges related to the modifications and restricted stock explained above, in the consolidated statement of income for the three and nine month periods ended June 30, 2006 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 of \$1,042,000 in the three month period ended June 30, 2006 as follows: \$206,000 to research and development and \$836,000 to marketing, general and administrative expense. We allocated these noncash expenses of \$3,461,000 in the nine month period ended June 30, 2006 as follows: \$558,000 to research and development and \$2,903,000 to marketing, general and administrative expense. As of June 30, 2006, there remained approximately \$6,340,000 of compensation costs related to non-vested stock options to be recognized over a weighted-average period of approximately 1.3 years.

Presented below is our stock option activity:

	June 30, 2006		Nine Months Ended		June 30, 2005	
	Shares	Weighted Average Exercise Price	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	546,250	\$ 4.76	1,220,500	\$ 4.02		
Exercised	(323,376)	\$ 3.13	(209,123)	\$ 2.51		
Cancelled	(224,104)	\$ 4.84	(229,873)	\$ 6.27		
Outstanding at end of period	11,847,065	\$ 4.53	11,713,296	\$ 4.51		
Options exercisable at end of period	9,422,326	\$ 4.46	8,671,160			
Weighted average fair value of options granted		\$ 2.98		\$ 2.40		

At June 30, 2006, stock options were outstanding and exercisable as follows:

Range of Exercise Price	Shares	Outstanding Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable	
				Shares	Weighted Average Exercise Price
\$1.22-\$ 2.71	3,096,002	4.0 years	\$ 2.29	2,920,002	\$ 2.27
\$2.77-\$ 4.16	3,426,001	5.5 years	\$ 3.67	2,452,229	\$ 3.85
\$4.26-\$ 6.19	3,626,469	4.2 years	\$ 5.94	3,057,657	\$ 6.01
\$6.21-\$20.13	1,698,594	7.2 years	\$ 7.33	992,438	\$ 7.63
\$1.22-\$20.13	11,847,066	5.0 years	\$ 4.53	9,422,326	\$ 4.46

The aggregate intrinsic value of outstanding options as of June 30, 2006 was \$15,500,000, of which \$12,900,000 was related to exercisable options. The intrinsic value of options exercised during the three months ended June 30, 2005 was \$12,000. No options were exercised during the three months ended June 30, 2006. The intrinsic value of options exercised during the nine months ended June 30, 2006 and 2005 was \$1,037,000 and \$912,000, respectively. The intrinsic value of options vested during the three and nine months ended June 30, 2006 was \$432,000 and \$784,000 respectively. The weighted average contractual life for total options exercisable at June 30, 2006 is approximately 4.1 years.



## **Table of Contents**

The aggregate intrinsic value of restricted stock awards outstanding as of June 30, 2006 was \$1,181,000 for awards with service based vesting criteria and from \$1,153,000 to \$1,921,000 for contingently issuable awards with service and market based vesting criteria.

### *Insurance Claim Receivable*

As of June 30, 2006, we had an outstanding insurance claim of approximately \$3,700,000, for services rendered through May 30, 2001 by the group of law firms defending us in the Redux-related product liability litigation. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company ( Reliance ), which is in liquidation proceedings. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately \$2,400,000 against the insurance claim on Reliance as of June 30, 2006 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 June 30, 2006, 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 June 30, 2006. 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 certain royalties owed by us. Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from partners, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities. In addition, for the nine month period ended June 30, 2005, contract and license fee revenue also included reimbursements from our SANCTURA marketing partner for their share of SANCTURA promotion and advertising costs incurred by us less an amount owed by us to our SANCTURA marketing partner for our 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 our licensed technologies and are generally reported to us in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, we recognize such royalty revenue in the subsequent accounting period when we receive 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 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,

## **Table of Contents**

the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. In multiple element arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as we complete our performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. We record such revenue as contract and license fee revenue.

Revenues from milestone payments, related to arrangements under which we have continuing performance obligations, are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. We record 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 for 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 SEC 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 our 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 increased \$3,588,000, or 37%, to \$(13,377,000), or \$(0.28) per share, basic, in the three month period ended June 30, 2006 from \$(9,789,000), or \$(0.21) per share, basic, in the three month period ended June 30, 2005 and decreased \$4,125,000, or 10%, to \$(36,533,000), or \$(0.77) per share, basic, in the nine month period ended June 30, 2006 from \$(40,658,000), or \$(0.87) per share, basic, in the nine month period ended June 30, 2005. The decreased net loss in the nine month period ended June 30, 2006 is primarily the result of our decreased marketing expenses and increased royalties and sales force subsidy related to SANCTURA,

## **Table of Contents**

partially offset by increased research and development expense substantially related to trospium and noncash charges relating to our adoption of SFAS 123R. SANCTURA marketing costs became the sole responsibility of our marketing partner and the sales force subsidy commenced on November 29, 2004 pursuant to the Conversion.

Total revenues increased \$3,686,000, or 45%, to \$11,879,000 in the three month period ended June 30, 2006 from \$8,193,000 in the three month period ended June 30, 2005 and increased \$12,043,000, or 52%, to \$35,276,000 in the nine month period ended June 30, 2006 from \$23,233,000 in the nine month period ended June 30, 2005. The increase in the three month period ended June 30, 2006 is primarily due to higher shipments of SANCTURA to our marketing partner and net sales of DELATESTRYL. The increase in the nine month period ended June 30, 2006 is primarily due to SANCTURA-related revenues and net sales of DELATESTRYL.

Product revenues increased \$3,151,000, or 100%, to \$6,294,000 in the three month period ended June 30, 2006 from \$3,143,000 in the three month period ended June 30, 2005 and increased \$6,318,000, or 58%, to \$17,166,000 in the nine month period ended June 30, 2006 from \$10,848,000 in the nine month period ended June 30, 2005. Sales of SANCTURA to our marketing partner increased \$2,554,000 to \$3,316,000 in the three month period ended June 30, 2006 from \$762,000 in the three month period ended June 30, 2005 and increased \$3,193,000 to \$9,032,000 in the nine month period ended June 30, 2006 from \$5,839,000 in the nine month period ended June 30, 2005. Sales of SANCTURA to our marketing partner are dependent upon the timing of our partner's orders which can vary from period to period. Royalties from SANCTURA decreased \$211,000 to \$1,758,000 in the three month period ended June 30, 2006 from \$1,969,000 in the three month period ended June 30, 2005 and increased \$1,565,000 to \$5,273,000 in the nine month period ended June 30, 2006 from \$3,708,000 in the nine month period ended June 30, 2005. Royalties in the fiscal 2006 periods reflected the minimum royalties due pursuant to the SANCTURA Agreement which exceeded royalties calculated on net sales of SANCTURA. There were no minimum royalties in the fiscal 2005 periods. We expect royalty revenue from SANCTURA in fiscal 2006 will continue to reflect such minimum royalties, which increase to \$7,875,000 annually for the royalty year commencing July 1, 2006. Additionally, product revenue included net sales of DELATESTRYL of \$850,000 and \$1,866,000 in the three and nine month periods ended June 30, 2006, respectively.

Contract and license fee revenues relate almost entirely to the SANCTURA Agreement and increased \$535,000, or 11%, to \$5,585,000 in the three month period ended June 30, 2006 from \$5,050,000 in the three month period ended June 30, 2005 and increased \$5,725,000, or 46%, to \$18,110,000 in the nine month period ended June 30, 2006 from \$12,385,000 in the nine month period ended June 30, 2005. Sales force subsidy pursuant to the SANCTURA Agreement increased \$268,000 to \$2,188,000 in the three month period ended June 30, 2006 from \$1,920,000 in the three month period ended June 30, 2005 and \$2,084,000 to \$6,563,000 in the nine month period ended June 30, 2006 from \$4,479,000 in the nine month period ended June 30, 2005. The fiscal 2006 periods reflected slightly higher subsidy rates than the fiscal 2005 periods and the nine month period ended June 30, 2006 included nine months of subsidy compared to only seven months of subsidy in the nine month period ended June 30, 2005. The nine month period ended June 30, 2005 included a \$1,489,000 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 nine month period ended June 30, 2006 resulted in an increase in contract and license fee revenue. After the copromotion period ended November 28, 2004, PLIVA became responsible for promotion and advertising costs. The nine month period ended June 30, 2006 included \$1,266,000 of contract and license fee revenue, \$1,000,000 of which was received in cash, from the amended bucindolol license agreement. 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 June 30, 2006 and 2005, respectively, and \$10,062,000 and \$9,375,000 in the nine month periods ended June 30, 2006 and 2005, respectively.

Cost of product revenue increased \$2,812,000, or 150%, to \$4,686,000 in the three month period ended June 30, 2006 from \$1,874,000 in the three month period ended June 30, 2005 and increased \$4,607,000, or 60%, to \$12,336,000 in the nine month period ended June 30, 2006 from \$7,729,000 in the nine month period ended

## **Table of Contents**

June 30, 2005. These increases are primarily due to the increases in sales of SANCTURA product sold to our marketing partner at our cost to manufacture and cost of DELATESTRYL sold of \$814,000 and \$1,773,000 in the three and nine month periods ended June 30, 2006, respectively, partially offset by decreased royalties to Madaus, licensor of SANCTURA to us.

Research and development expense increased \$5,570,000, or 100%, to \$11,129,000 in the three month period ended June 30, 2006 from \$5,559,000 in the three month period ended June 30, 2005 and \$13,435,000, or 77%, to \$30,883,000 in the nine month period ended June 30, 2006 from \$17,448,000 in the nine month period ended June 30, 2005. These increases are primarily due to increased external product development costs of approximately \$4,400,000 and \$11,300,000 in the three and nine month periods ended June 30, 2006, respectively. External development costs related to trospium increased approximately \$3,200,000 and \$10,500,000 in the three and nine month periods ended June 30, 2006, respectively, and related primarily to our Phase III clinical development program for SANCTURA XR initiated in September 2005. Pagoclone external development costs related primarily to our Phase II clinical trial for stuttering increased approximately \$300,000 and \$1,600,000 in the three and nine month periods ended June 30, 2006, respectively and NEBIDO external development costs increased approximately \$1,200,000 and \$1,500,000 in the three and nine month periods ended June 30, 2006, respectively. The three and nine month periods ended June 30, 2006 also included an \$800,000 expense related to a milestone earned by our SANCTURA XR development partner, Supernus Pharmaceuticals, Inc., which was formerly known as Shire Laboratories Inc. Partially offsetting these increases is decreased external development costs related to aminocandin of approximately \$1,100,000 and \$3,300,000 in the three and nine month periods ended June 30, 2006, respectively. Additionally, employee and compensation related expense increased approximately \$400,000 and \$1,300,000 in the three and nine month periods ended June 30, 2006, respectively, related to additional staffing and noncash stock-based compensation expense from the adoption of SFAS 123R.

Marketing, general and administrative expense decreased \$137,000, or 2%, to \$8,908,000 in the three month period ended June 30, 2006 from \$9,045,000 in the three month period ended June 30, 2005 and decreased \$7,988,000, or 23%, to \$26,725,000 in the nine month period ended June 30, 2006 from \$34,713,000 in the nine month period ended June 30, 2005. Marketing expense decreased \$59,000, or 1%, to \$4,723,000 in the three month period ended June 30, 2006 from \$4,782,000 in the three month period ended June 30, 2005 and decreased \$9,271,000, or 38%, to \$14,835,000 in the nine month period ended June 30, 2006 from \$24,105,000 in the nine month period ended June 30, 2005. The decrease in marketing expense in the nine month period reflected approximately \$7,100,000 of decreased promotion and advertising expense related to SANCTURA and approximately \$3,600,000 of decreased sales force-related expense. As noted above, after the copromotion period ended November 29, 2004 pursuant to the Conversion, PLIVA became responsible for promotion and advertising costs and we transferred approximately 200 primary care sales representatives to PLIVA. Partially offsetting these decreases were increased expenses primarily related to the marketing of DELATESTRYL, noncash option compensation expense from the adoption of SFAS 123R and other marketing and sales related activities. In January 2006, the sales force commenced promoting DELATESTRYL in addition to SANCTURA.

General and administrative expense decreased \$78,000, or 2%, to \$4,185,000 in the three month period ended June 30, 2006 from \$4,263,000 in the three month period ended June 30, 2005 and increased \$1,282,000, or 12%, to \$11,890,000 in the nine month period ended June 30, 2006 from \$10,608,000 in the nine month period ended June 30, 2005. The three month period change included a decrease of approximately \$1,300,000 related a charge recorded in the three month period ended June 30, 2005 related to the nonutilization of our prior facilities and increases for noncash option compensation expense from the adoption of SFAS 123R of approximately \$600,000, legal fees of approximately \$400,000 and compensation expense of approximately \$300,000 related primarily to increased staffing. The increase in the nine month period is primarily due to noncash option compensation expense from the adoption of SFAS 123R of approximately \$2,300,000, increased compensation expense of approximately \$500,000 related primarily to increased staffing and increased legal fees of approximately \$400,000, offset by the approximately \$1,300,000 facilities charge described above and a credit of approximately \$300,000 resulting from the subsequent settlement of our accrued lease obligation.

## **Table of Contents**

Investment income decreased \$38,000, or 5%, to \$760,000 in the three month period ended June 30, 2006 from \$798,000 in the three month period ended June 30, 2005 and increased \$238,000, or 11%, to \$2,448,000 in the nine month period ended June 30, 2006 from \$2,210,000 in the nine month period ended June 30, 2005 reflecting higher interest rates and reduced average invested balances in the fiscal 2006 periods from the fiscal 2005 periods.

Interest expense of \$1,293,000 in the three month periods and \$3,878,000 in the nine month periods 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 \$5,170,000, which includes approximately \$700,000 of amortization of debt issuance costs.

The provision for income taxes of \$1,000,000 and \$2,150,000 in the three and nine month periods ended June 30, 2005 relates to U.S. federal alternative minimum tax and state income tax. Tax recognition of the initial and milestone payments received from PLIVA in fiscal 2004 were deferred to fiscal 2005 when they were recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. federal alternative tax and by certain states resulting in federal and state tax obligations in fiscal 2005.

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

## **Liquidity and Capital Resources**

On July 3, 2006, we closed our underwritten public offering of common stock. We issued 8,050,000 shares, including 1,050,000 shares to cover underwriter over allotments, at a price to the public of \$4.65 per share. Our net proceeds after underwriting commissions and expenses were approximately \$34,800,000. This offering of common stock was made pursuant to an effective shelf registration statement filed with the SEC on December 28, 2005.

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

At June 30, 2006 we had consolidated cash, cash equivalents and marketable securities of \$53,325,000 compared to \$101,217,000 at September 30, 2005. This decrease of \$47,892,000 is primarily the result of net cash used in operating activities of \$49,068,000 (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 \$5,600,000 to Savient related to our purchase of DELATESTRYL and will pay approximately \$2,400,000 additionally, including our assumption of Savient's previous obligation to purchase \$1,100,000 of additional 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 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.

There remains 1,950,000 shares issuable pursuant to the shelf registration statement on Form S-3 we filed with the SEC on December 28, 2005. The registration statement remains effective. Such remaining shares of our common stock may be offered from time to time through one or more methods of distribution, subject to market conditions and our capital needs. The terms of any offerings would be established at the time of the offering. Currently, we do not have any commitments to sell such shares remaining under the registration statement.

## **Table of Contents**

### **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 \$45,000,000 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 \$35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the \$20,000,000 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 U.S. current Good Manufacturing Practices, 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 June 30, 2006 on the major compounds currently being developed or marketed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: \$124,400,000 for SANCTURA and SANCTURA XR, \$14,000,000 for NEBIDO, \$16,600,000 for PRO 2000, \$5,800,000 for IP 751, \$29,500,000 for pagoclone, and \$11,100,000 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 June 30, 2006 through the preparation of an NDA for our major compounds currently being developed as follows: approximately \$9,000,000 for SANCTURA XR, \$12,000,000 for NEBIDO, \$17,000,000 for PRO 2000, approximately \$47,000,000 for IP 751, approximately \$40,000,000 for pagoclone for stuttering, and approximately \$35,000,000 for pagoclone for premature ejaculation. We do not expect to conduct significant additional development of aminocandin without a development and marketing partner. Currently estimated research and developments costs through the preparation of an NDA for aminocandin are approximately \$86,000,000. 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**

Net cash used in operating activities in the nine month period ended June 30, 2006 of \$49,068,000 consisted primarily of the net loss of \$36,533,000. Contributing to cash used in operating activities is an \$11,497,000 decrease of deferred revenue consisting of \$10,063,000 of amortization into contract and license fee revenue and \$1,434,000 recognized as product revenue for shipments of SANCTURA to our marketing partner. Also contributing to cash used in operating activities is a \$9,930,000 increase in inventories, \$5,408,000 of which



---

**Table of Contents**

relates to DELATESTRYL and \$4,522,000 relates to SANCTURA awaiting packaging and shipment to Esprit. Partially offsetting these uses of cash in operating activities is an increase in accounts payable and accrued expenses and other liabilities totaling \$9,589,000 related to increased level of business activity and timing of payments and noncash compensation of \$3,461,000 related to stock compensation expense pursuant to our adoption of SFAS 123R.

Net cash provided by investing activities of \$6,985,000 is primarily comprised of maturities and sales of marketable securities of \$7,119,000.

Net cash provided by financing activities of \$1,310,000 resulted from net proceeds from the issuance of treasury stock pursuant to our stock option and employee stock purchase plans. We cannot predict if or when stock options will be exercised in the future.

**Contractual Obligations and Off-Balance Sheet Arrangements**

Pursuant to our agreement with Madaus GmbH ( Madaus ), 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.

Pursuant to the DELATESTRYL Agreement, we assumed Savient's previous obligation to purchase approximately \$1,100,000 of additional DELATESTRYL inventory. We expect this purchase to occur in fiscal 2006.

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 generally cannot predict if or when such events will occur. In the three and nine month period ended June 30, 2006 we recorded a license payment obligation to Madaus and intangible asset of \$1,500,000 in recognition of expected achievement of a contingent cumulative net sales milestone related to SANCTURA. We will amortize the intangible asset to cost of revenue over the remaining term of the Madaus license agreement and pay the milestone when it is achieved.

During the nine month period ended June 30, 2006, we settled the remaining lease obligations relating to our prior office facility for a payment of \$500,000 and reflected a credit of approximately \$300,000 in marketing, general, and administrative expense related to the extinguishment of our accrued liability.

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. 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. We will adopt this pronouncement beginning October 1, 2006.

## **Table of Contents**

In July 2006, the FASB issued FIN 48. FIN 48 clarifies the accounting for uncertain tax positions as described in SFAS No. 109, Accounting for Income Taxes, and requires a company to recognize, in its financial statements, the impact of a tax position only if that position is more likely than not of being sustained on an audit basis solely on the technical merit of the position. In addition, FIN 48 requires qualitative and quantitative disclosures including a discussion of reasonably possible changes that might occur in the recognized tax benefits over the next twelve months as well as a roll-forward of all unrecognized tax benefits. FIN 48 is effective for fiscal years beginning after December 15, 2006. We intend to adopt FIN 48 beginning October 2007 and are currently evaluating the impact FIN 48 might have on its consolidated results of operations and financial condition.

### ***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 \$1,000 Note by approximately \$50. 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 \$1,000 Note by approximately \$10. 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.

### ***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 June 30, 2006, 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 June 30, 2006 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

## **Table of Contents**

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 June 30, 2006 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.

Since the withdrawal of Redux, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. To date, there have been no judgments against us, nor have we paid any amounts in settlement of any of these claims. The actions generally have been brought by individuals in their own right or on behalf of putative classes of persons who claim to have suffered injury or who claim that they may suffer injury in the future due to use of one or more weight loss drugs including Pondimin (fenfluramine), phentermine and Redux. Plaintiffs' allegations of liability are based on various theories of recovery, including, but not limited to, product liability, strict liability, negligence, various breaches of warranty, conspiracy, fraud, misrepresentation and deceit. These lawsuits typically allege that the short or long-term use of Pondimin and/or Redux, independently or in combination (including the combination of Pondimin and phentermine, popularly known as "fen-phen"), causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. In addition, some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of the individual or the class. In addition, some actions seeking class certification ask for certain types of purportedly equitable relief, including, but not limited to, declaratory judgments and the establishment of a research program or medical surveillance fund. On December 10, 1997, the federal Judicial Panel on Multidistrict Litigation issued an Order allowing for the transfer or potential transfer of the federal actions to the Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings.

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth, formerly American Home Products Corporation, pursuant to which Wyeth has agreed to indemnify us against certain classes of product liability cases filed against us related to Redux. Our indemnification covers plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs related to our defense of Redux-related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to

## **Table of Contents**

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**

- 3.1 Restated Certificate of Incorporation of Registrant, as amended (1)
- 3.2 By-Laws of Registrant (2)
- 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 (3)
- 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 (3)
- 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 (3)
- 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 (3)

- 
- (1) Incorporated by reference to Registrant's Annual Report on Form 10-K for the fiscal year ended September 30, 2005.
  - (2) Incorporated by reference to Registrant's Form 8-K filed July 3, 2003.
  - (3) Filed with this report.

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC.

Date: August 4, 2006

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

INDEVUS PHARMACEUTICALS, INC.

Date: August 4, 2006

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

INDEVUS PHARMACEUTICALS, INC.

Date: August 4, 2006

By: /s/ Dale Ritter  
Dale Ritter, Senior Vice President, Finance (Principal  
Accounting Officer)