

INDEVUS PHARMACEUTICALS INC

Form 10-Q

May 02, 2008

[Table of Contents](#)

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 2008

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)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

**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)

**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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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.

**Class:**  
**Common Stock \$.001 par value**

**Outstanding at April 30, 2008**  
**77,508,767 shares**

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

**INDEX TO FORM 10-Q**

	<b>PAGE</b>
<b>PART I. FINANCIAL INFORMATION (unaudited)</b>	
Item 1. Financial Statements	
<u>Consolidated Balance Sheets as of March 31, 2008 and September 30, 2007</u>	3
<u>Consolidated Statements of Operations for the Three and Six Months ended March 31, 2008 and 2007</u>	4
<u>Consolidated Statements of Cash Flows for the Six Months ended March 31, 2008 and 2007</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
Item 4. <u>Controls and Procedures</u>	26
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	26
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	27
Item 6. <u>Exhibits</u>	28
SIGNATURES	29

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

	<b>March 31, 2008</b>	<b>September 30, 2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 60,765	\$ 71,142
Accounts receivable, net	11,737	7,249
Inventories, net	11,344	7,729
Prepaid and other current assets	3,548	4,708
<b>Total current assets</b>	<b>87,394</b>	<b>90,828</b>
Property, plant and equipment, net	10,952	9,771
Inventories, net	809	682
Goodwill	48,244	48,244
Intangible assets, net	28,197	29,190
Other assets	4,484	4,335
<b>Total assets</b>	<b>\$ 180,080</b>	<b>\$ 183,050</b>
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$ 7,727	\$ 4,505
Accrued expenses	18,162	24,704
Accrued interest	950	950
Deferred revenue	42,202	21,946
Convertible notes	75	75
<b>Total current liabilities</b>	<b>69,116</b>	<b>52,180</b>
Convertible notes	69,089	68,037
Deferred revenue	142,260	136,515
Other	916	656
<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 at March 31, 2008 of \$3,030)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference at March 31, 2008 of \$505)	500	500
Common Stock, \$.001 par value, 200,000,000 shares authorized; 76,891,629 and 76,360,039 shares issued and outstanding at March 31, 2008 and September 30, 2007, respectively	76	76
Additional paid-in capital	504,233	498,587
Accumulated deficit	(609,110)	(576,501)
<b>Total stockholders deficit</b>	<b>(101,301)</b>	<b>(74,338)</b>
<b>Total liabilities and stockholders deficit</b>	<b>\$ 180,080</b>	<b>\$ 183,050</b>

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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 six months ended March 31, 2008 and 2007****(Unaudited)****(Amounts in thousands except per share data)**

	<b>Three months ended March 31,</b>		<b>Six months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>				
Product revenue	\$ 7,209	\$ 3,455	\$ 14,507	\$ 8,712
Contract and license fees	10,434	7,769	19,535	15,663
<b>Total revenues</b>	<b>17,643</b>	<b>11,224</b>	<b>34,042</b>	<b>24,375</b>
<b>Costs and expenses:</b>				
Cost of revenues	6,412	1,274	12,267	5,550
Research and development	6,253	9,272	12,645	19,191
Marketing, general and administrative	21,276	12,687	39,042	21,690
Amortization of intangibles	497		993	
<b>Total costs and expenses</b>	<b>34,438</b>	<b>23,233</b>	<b>64,947</b>	<b>46,431</b>
<b>Loss from operations</b>	<b>(16,795)</b>	<b>(12,009)</b>	<b>(30,905)</b>	<b>(22,056)</b>
Investment income	650	863	1,769	1,903
Interest expense	(1,761)	(1,293)	(3,473)	(2,585)
<b>Net loss</b>	<b>\$ (17,906)</b>	<b>\$ (12,439)</b>	<b>\$ (32,609)</b>	<b>\$ (22,738)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.23)</b>	<b>\$ (0.22)</b>	<b>\$ (0.43)</b>	<b>\$ (0.41)</b>
<b>Weighted average common shares outstanding, basic and diluted</b>	<b>76,461</b>	<b>55,923</b>	<b>76,383</b>	<b>55,885</b>

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 six months ended March 31, 2008 and 2007**

**(Unaudited)**

**(Amounts in thousands)**

	<b>For the six months ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (32,609)	\$ (22,738)
<b>Adjustments to reconcile net loss to net cash (used in) operating activities:</b>		
Depreciation and amortization	2,002	130
Note discount amortization	1,211	330
Noncash stock-based compensation	3,276	2,645
Lease abandonment	442	
Inventory impairment		1,100
<b>Changes in assets and liabilities, net of assets and liabilities acquired:</b>		
Accounts receivable	(4,488)	(1,153)
Inventories	(3,742)	848
Prepaid and other assets	808	859
Accounts payable	3,222	(1,001)
Accrued expenses and other liabilities	(6,690)	3,582
Deferred revenue	26,001	775
<b>Net cash (used in) operating activities</b>	<b>(10,567)</b>	<b>(14,623)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(2,191)	(186)
Proceeds from maturities and sales of marketable securities		5,956
Prepaid acquisition costs		(3,113)
<b>Net cash (used in) provided by investing activities</b>	<b>(2,191)</b>	<b>2,657</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock	2,381	806
<b>Net cash provided by financing activities</b>	<b>2,381</b>	<b>806</b>
<b>Net change in cash and cash equivalents</b>	<b>(10,377)</b>	<b>(11,160)</b>
Cash and cash equivalents at beginning of period	71,142	70,169
<b>Cash and cash equivalents at end of period</b>	<b>\$ 60,765</b>	<b>\$ 59,009</b>

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, 2007.

Indevus is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company s approved products include SANCTUR<sup>®</sup> and SANCTURA XR for overactive bladder ( OAB ), co-promoted with its partner Allergan, Inc. ( Allergan ), VANTAS<sup>®</sup> for advanced prostate cancer, SUPPRELIN<sup>®</sup> LA for central precocious puberty ( CPP ), and DELATESTRYL<sup>®</sup> for the treatment of hypogonadism. The Company markets its products through an approximately 100-person specialty sales force.

The Company s core urology and endocrinology portfolio contains multiple compounds in development in addition to its approved products. The Company s most advanced compounds are VALSTAR<sup>™</sup> for bladder cancer, NEBIDO<sup>®</sup> for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, the octreotide implant for acromegaly and a biodegradable ureteral stent for the adjunctive treatment of kidney stones.

In addition to the Company s core urology and endocrinology portfolio, there are multiple compounds outside of its core focus area which the Company either currently outlicenses for development and commercialization, or intends to outlicense in the future. These compounds include pagoclonerone for stuttering, ALKS 27 for chronic obstructive pulmonary disease ( COPD ) which the Company has been jointly developing with Alkermes, Inc. ( Alkermes ), aminocandin for systemic fungal infections for which the Company licensed worldwide rights to Novoxel S.A. ( Novoxel ) and IP 751 for pain and inflammation for which the Company licensed worldwide rights to Cervelo Pharmaceuticals, Inc. ( Cervelo ).

On April 18, 2007, the Company acquired Valera Pharmaceuticals, Inc. ( Valera ), a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products (the Valera Acquisition ) (see Note C). The Valera Acquisition was accounted for under the purchase method of accounting and the results of operations of Valera have been included in the consolidated results of the Company from the acquisition date.

*B. Accounting Policies*

*Revenue Recognition:* The Company classifies all revenue as product revenue or contract and license fee revenue. Any consideration received in advance of revenue recognition is recorded as deferred revenue. Product revenue consists primarily of revenues from sales of products, royalties and reimbursements for royalties owed by the Company. Product sales are generally recognized as revenue upon the later of shipment or title transfer to the Company s customers. Sales of VANTAS and DELATESTRYL are recorded net of reserves for returns, rebates and allowances. For SUPPRELIN LA, where chargebacks, insurance reimbursement or refunds cannot be reasonably estimated, revenue is deferred until such amounts are known and recorded as product revenue net of reserves for rebates and allowances. Until October 16, 2007, the effective date of the Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharmaceuticals Inc., which was simultaneously acquired by Allergan, Inc., (the Allergan Agreement ), the Company recorded sales of SANCTURA to its marketing partner as product sales. Subsequent to the Allergan Agreement, the Company determined that the arrangement represented a single unit of accounting and began aggregating all of the proceeds from sales of SANCTURA and SANCTURA XR with all of the other consideration received from Allergan, recording it all as deferred revenue and recognizing it as contract and license fee revenue using the appropriate revenue recognition model.

Royalty revenue consists of payments received from licensees for a portion of the sales proceeds from products that utilize the Company s licensed technologies. Royalties are generally reported to the Company in a royalty report on a specified periodic basis and recognized in the period in which the sales of the product or technology on which the royalties are based occurred. If the royalty report for such period is received subsequent to the time when 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, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount



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

of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

---

**Table of Contents**

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments. The Company's business strategy includes entering into collaborative license, development, supply and 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 resulting from the achievement of certain milestones and royalties on net product sales.

Many of the Company's agreements contain multiple elements and require evaluation 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 the Company has continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered elements in the arrangement. In the case of an arrangement where it is determined that there is a single unit of accounting, all cash flows from the arrangement are aggregated and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. The Company records such revenue as contract and license fee revenue.

Certain multiple element arrangements include provisions for the Company to participate on various committees, such as steering committees, development committees, and commercialization committees. The Company evaluates the facts and circumstances of the arrangement to determine if its participation is protective of the Company's interests or if it constitutes a deliverable to be included in the Company's evaluation of the arrangement under EITF 00-21. Additionally, pursuant to the guidance in Securities and Exchange Commission Bulletin (SAB) No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected period of the arrangements during which the Company has continuing performance obligations.

The Company has elected to use the proportional performance model to determine recognition of revenue related to multiple element arrangements determined to be single units of accounting where the Company has continuing performance obligations and can estimate the completion of its earnings process. Under the Allergan Agreement, because the Company cannot determine the total amount of expected revenue or the pattern by which it will complete its obligations, all consideration is recognized as contract and license fee revenue using the Contingency-Adjusted Performance Model (CAPM). Under this model, when a portion of the consideration under the arrangement 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 Allergan Agreement to the time the milestone is earned over the estimated performance period of the Allergan Agreement. Thereafter, the remaining portion of the consideration is recognized on a straight-line basis over the remaining estimated performance period of the Allergan Agreement. In other multiple element arrangements where the Company can estimate its expected revenue and measure its completion of the earnings process, the Company utilizes the proportional performance model.

In multiple element arrangements, where the Company has separate units of accounting, revenues from milestone payments related to arrangements under which the Company has no 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.

*Cash, Cash Equivalents and Marketable Securities:* The Company invests available cash primarily in short-term bank deposits, money market funds, repurchase agreements, domestic and foreign commercial paper and government securities. Cash and cash equivalents include investments with original maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date and are not considered available to fund current operations. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices. At March 31, 2008 and September 30, 2007, the Company had no marketable securities.

**Table of Contents**

*Inventory:* Inventories are stated at the lower of cost or market with cost determined under the first in, first out ( FIFO ) method. Included in inventory costs are materials, drug costs, direct labor and manufacturing overheads that include facility costs and indirect manufacturing costs. The Company expenses costs related to inventory until such time as it receives approval from the FDA to market a product, at which time the Company commences capitalization of costs relating to that product.

*Accounting for Stock-Based Compensation:* The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted SFAS 123R, *Accounting for Stock-Based Compensation* ( SFAS 123R ). 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 Company is required to make significant estimates related to SFAS 123R. The Company's expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended March 31, 2008 and 2007, the Company used a weighted-average expected stock-price volatility of 49.5% and 60.6%, respectively. For stock option grants issued to non-executives during the six months ended March 31, 2008 and 2007, the Company used a weighted-average expected stock-price volatility of 49.1% and 60.7%, respectively. For stock option grants to executives during the three months ended March 31, 2008 and 2007, the Company used a weighted average expected stock-price volatility of 52.9% and 64.0%, respectively. For stock option grants to executives during the six months ended March 31, 2008 and 2007, the Company used weighted average expected stock-price volatility ranges of 50.0% to 52.9% and 62.8% to 64.0%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. The Company 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 months ended March 31, 2008 and 2007, the Company used a weighted-average expected option life assumption of 6.50 and 6.25 years, respectively, for non-executives and 8.0 years for executives. For stock option grants made during the six months ended March 31, 2008 and 2007, the Company used a weighted-average expected option life assumption of 6.47 years for non-executives and 8.0 years for executives. A shorter expected term would result in lower compensation expense.

*Use of Estimates:* The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

*C. Valera Acquisition*

On April 18, 2007, the Company completed the Valera Acquisition. The Company acquired 100% of the outstanding stock of Valera in a tax-free stock-for-stock merger initially valued at approximately \$128,544,000, plus contingent stock rights ( CSRs ) related to three of Valera's product candidates in development at the time of the Valera Acquisition. At the date of the acquisition, approximately 17,693,000 shares of Indevus Common Stock were issued.

Valera common stockholders received three CSRs for each share of Valera Common Stock and the option holders who consented to the proposed treatment of such options received three unfunded and unsecured promises to receive shares of Indevus Common Stock ( CSR Equivalents ). The CSRs convert to \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus Common Stock upon the FDA approval to market SUPPRELIN LA, a biodegradable stent and an octreotide implant, respectively. The CSRs and CSR Equivalents related to SUPPRELIN LA became payable on May 3, 2007, upon announcement of the regulatory approval of SUPPRELIN LA, and 2,251,000 shares of Indevus Common Stock became issuable. The additional purchase price related to achievement of this milestone was \$16,522,000 and was recorded as an increase to goodwill. The remaining CSRs and CSR Equivalents will become payable in shares of Indevus Common Stock only if the applicable milestones for the biodegradable ureteral stent and octreotide implant are achieved within five years of the closing of the merger. If both remaining CSR milestones are achieved, the Company will issue Common Stock totaling approximately \$40,600,000 in value, which will have the effect of increasing goodwill by an equivalent amount.

The Valera Acquisition was accounted for under the purchase method of accounting and the results of operations of Valera have been included in the consolidated results of the Company from the acquisition date. The purchase price of the acquisition was allocated to tangible and intangible assets and liabilities assumed based on their estimated fair values at the date of acquisition. The purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by \$48,244,000, which was classified as goodwill.

**Table of Contents**

The following represents the unaudited pro forma results of the ongoing operations for Indevus and Valera as though the acquisition of Valera had occurred at the beginning of the three and six month periods ended March 31, 2007. As a result, the pro forma financial information for the three and six months ended March 31, 2007 includes nonrecurring adjustments of \$50,000,000 for IPR&D expense and \$1,227,000 for stock compensation expense for the acceleration of vesting of Valera stock options. The unaudited pro forma information, however, is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results.

	<b>Three months ended March 31, 2007 (Pro forma)</b>	<b>Six months ended March 31, 2007 (Pro forma)</b>
Revenue	\$ 14,463,000	\$ 30,818,000
Net loss	\$ (70,935,000)	\$ (86,389,000)
Net loss per common share (basic and diluted)	\$ (0.93)	\$ (1.14)

*D. 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>March 31, 2008</b>	<b>September 30, 2007</b>
Raw materials	\$ 5,531,000	\$ 771,000
Work in process	3,871,000	4,405,000
Finished goods	2,751,000	3,235,000
	\$ 12,153,000	\$ 8,411,000

All of the Company's inventories at the balance sheet date relate to commercially approved products: SANCTURA XR, VANTAS, SUPPRELIN LA and DELATESTRYL. The Company has classified \$809,000 and \$682,000 of DELATESTRYL inventory as noncurrent as of March 31, 2008 and September 30, 2007, respectively.

*E. Property, Plant and Equipment*

Property, plant and equipment consisted of the following:

	<b>Useful Lives</b>	<b>March 31, 2008</b>	<b>September 30, 2007</b>
Manufacturing and office equipment	2 - 7 years	\$ 5,180,000	\$ 4,373,000
Leasehold improvements	5 - 10 years	6,800,000	6,309,000
Construction in progress		1,904,000	1,011,000
		13,884,000	11,693,000
Less: accumulated depreciation and amortization		(2,932,000)	(1,922,000)
Property, plant and equipment, net		\$ 10,952,000	\$ 9,771,000

Depreciation and amortization expense for property, plant and equipment was approximately \$523,000 and \$63,000 for the three months ended March 31, 2008 and 2007, respectively and approximately \$1,010,000 and \$130,000 for the six months ended March 31, 2008 and 2007, respectively.

*F. Basic and Diluted Loss per Common Share*

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

During the three month period ended March 31, 2008, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 6,969,000 shares of Common Stock at prices ranging from \$5.77 to \$8.72 with various expiration dates up to February 5, 2018. Additionally, during the three month period ended March 31, 2008, 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) \$71,925,000 of 6.25% Convertible Senior Notes due in 2009 and \$75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes), which are convertible into a total of 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes due in 2008 and through July 15, 2009 with respect to the Convertible Notes due in 2009; (ii) options to purchase 6,768,000 shares of Common Stock at prices ranging from \$1.22 to \$5.67 with various expiration dates up to March 4, 2018; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (iv) unvested restricted stock with service-based vesting criteria of 209,001 shares and unvested restricted stock awards with service and market-based vesting criteria of 330,350 to 566,300 contingently issuable shares; and (v) unvested deferred stock units with service vesting criteria of 100,000 shares of Common Stock.

**Table of Contents**

During the three month period ended March 31, 2007, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 1,130,000 shares of Common Stock at prices ranging from \$6.85 to \$8.72 with various expiration dates up to March 26, 2017. Additionally, during the three month period ended March 31, 2007, 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) the Convertible Notes, which were convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 11,180,000 shares of Common Stock at prices ranging from \$1.22 to \$6.72 with expiration dates up to March 19, 2017; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iv) unvested restricted stock with service-based vesting criteria of 265,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 255,750 to 426,250 contingently issuable shares.

During the six month period ended March 31, 2008, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 2,725,000 shares of Common Stock at prices ranging from \$6.64 to \$8.72 with various expiration dates up to January 2, 2018. Additionally, during the six month period ended March 31, 2008, 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) \$71,925,000 of 6.25% Convertible Senior Notes due in 2009 and \$75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes), which are convertible into a total of 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes due in 2008 and through July 15, 2009 with respect to the Convertible Notes due in 2009; (ii) options to purchase 10,890,000 shares of Common Stock at prices ranging from \$1.22 to \$6.58 with various expiration dates up to March 4, 2018; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (iv) unvested restricted stock with service-based vesting criteria of 209,001 shares and unvested restricted stock awards with service and market-based vesting criteria of 330,350 to 566,300 contingently issuable shares; and (v) unvested deferred stock units with service vesting criteria of 100,000 shares of Common Stock.

During the six month period ended March 31, 2007, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 1,182,000 shares of Common Stock at prices ranging from \$6.85 to \$8.72 with various expiration dates up to March 26, 2017. Additionally, during the six month period ended March 31, 2007, 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) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which were convertible through July 15, 2008; (ii) options to purchase 11,100,000 shares of Common Stock at prices ranging from \$1.22 to \$6.72 with various expiration dates up to March 19, 2017; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; 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 255,750 to 426,250 contingently issuable shares.

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.

*G. Agreements**Allergan/Esprit*

In September 2007, the Company entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. ( Esprit ), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, the Company received an up-front license fee, partially creditable by Allergan against future payments to the Company, of \$25 million, and approximately \$8 million as payment of the supply price for future deliveries of SANCTURA XR subject to purchase orders issued by Allergan. The Allergan Agreement also grants the Company the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately \$123 million over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. In addition, the Company will receive approximately \$9 million in annual sales force subsidy for fiscal year 2008 which can be extended for up to six months at the Company's option. Third-party royalties paid by the Company as a result of existing licensing, manufacturing

---

**Table of Contents**

and supply agreements associated with sales of SANCTURA and SANCTURA XR will also be reimbursed to the Company. The Company will also manufacture and supply SANCTURA XR through June 30, 2008, and SANCTURA through September 30, 2012, to Allergan at cost. The Company may also receive a long-term commercialization milestone payment of \$20 million related to generic competition. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR, which occurred in January 2008, or the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

Commencing on the effective date of the Allergan Agreement, the Company began recognizing the deferred revenue balances that existed on the effective date and the upfront license payment of \$25 million on a straight-line basis over the approximately 5 year obligation period of the agreement. All future payments received from Allergan during the 5 year obligation period of the agreement, including royalties, sales force reimbursement and product revenues, will be recognized using the contingency-adjusted performance model. All payments received after the 5 year obligation period of the agreement will be recognized as revenue when earned, provided that there are no remaining obligations.

Collectively through March 31, 2008 and pursuant to all agreements between the Company and PLIVA d.d. ( PLIVA ), Esprit and Allergan, the Company has received approximately \$338 million in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to the Company's marketing partners at its cost to manufacture.

*Plantex*

The Company has a supply agreement with Plantex USA Inc. whereby Plantex will supply the Company with Valrubicin, the active pharmaceutical ingredient for VALSTAR. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by June 30, 2008. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the United States, the Company will have annual minimum purchase requirements of \$1.0 million. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if VALSTAR is not approved by June 30, 2008.

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

In May 2001, the Company entered into the AHP Indemnity and Release Agreement pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine hydrochloride capsules) C-IV, a prescription anti-obesity compound withdrawn from the market in September 1997. This indemnification covers plaintiffs who initially opted out of Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth has agreed to fund all future legal costs related to the Company's defense of Redux-related product liability cases. Also, pursuant to the agreement, Wyeth has funded additional insurance coverage to supplement the Company's existing product liability insurance. The Company believes this total insurance coverage is sufficient to address its potential remaining Redux product liability exposure. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which the Company is not otherwise indemnified or covered under the AHP Indemnity and Release Agreement will not have a material adverse effect on the Company's future business, results of operations or financial condition or that the potential of any such claims would not adversely affect the Company's ability to obtain sufficient financing to fund operations. Up to the date of the AHP Indemnity and Release Agreement, the Company's defense costs were paid by, or subject to reimbursement to the Company from, the Company's product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Indevus by Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth's national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

At March 31, 2008, the Company has an accrued liability of approximately \$500,000 for Redux-related expenses, including legal expenses. The amount the Company ultimately pays could differ significantly from the amount currently accrued at March 31, 2008. To the extent the amount paid differs from the amount accrued, the Company will record a charge or credit to the statement of operations.

As of March 31, 2008, the Company had an outstanding insurance claim of approximately \$3,300,000, 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 ). During the three month period ended March 31, 2008, the Company received a partial





**Table of Contents**

payment of \$400,000 from Reliance pertaining to this claim. 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 \$858,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$858,000 reflected as a noncurrent insurance claim receivable at March 31, 2008. It is uncertain when, if ever, the Company will collect any of its \$3,300,000 of estimated remaining claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the \$5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

*I. Other*

At March 31, 2008 and September 30, 2007, accrued expenses consisted of the following:

	March 31, 2008	September 30, 2007
Compensation related	\$ 4,238,000	\$ 5,351,000
Manufacturing and production costs	3,269,000	2,243,000
Clinical and sponsored research	3,058,000	9,048,000
Sales and marketing	2,878,000	2,903,000
Professional fees	1,311,000	895,000
Milestone payment		1,500,000
Other	3,408,000	2,764,000
	\$ 18,162,000	\$ 24,704,000

*J. Income Taxes*

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company's historical losses from operations represent significant negative evidence that indicates the need for a valuation allowance. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset. If it is determined, based on future profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods.

The Company adopted FIN 48 on October 1, 2007. The implementation of FIN 48 did not have a material impact on the Company's consolidated financial statements or results of operations. The Company does not have any unrecognized tax benefits. As of March 31, 2008, the Company had federal and state net operating loss carryforwards and federal and state research and development ( R&D ) credit carryforwards, which may be available to offset future federal and state income tax liabilities. The Company has not completed a formal R&D credit study, however, no amounts related to R&D credit carryforwards are being presented as an uncertain tax position under FIN 48.

The Company files tax returns in the U.S. Federal jurisdiction and in various state and local jurisdictions. The Company currently does not have any federal, state or local audits in progress. With limited exceptions, the Company is no longer subject to federal, state or local examinations for years prior to 2004, however, carryforward attributes that were generated prior to 2004 may still be adjusted upon examination by state or local tax authorities if they either have been or will be used in a future period.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as a component of tax expense. This policy did not change as a result of the adoption of FIN 48. For the quarter ended March 31, 2008, the Company did not recognize any accrued interest and penalties in its consolidated statement of operations or its consolidated balance sheet.



---

**Table of Contents**

*K. Liquidity*

The Company is subject to risks common to companies in the specialty pharmaceutical industry including, but not limited to, development by its competitors of new technological innovations, dependence on key personnel, its ability to protect proprietary technology, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company's technologies, its ability to comply with FDA government regulations and approval requirements, its ability to grow its business and its ability to obtain adequate financing to fund its current and planned operations. The Company expects to continue to incur substantial expenditures for the development, commercialization and marketing of its products. The Company believes its current and expected cash resources are sufficient to fund its operations through approximately the middle of the first calendar quarter of 2009. The Company will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to the Company. The failure to raise such funds would result in the need to significantly curtail the Company's marketing activities and delay development efforts, which would have a material adverse effect on the Company.

*L. Subsequent Events*

(i) In April 2008, the Company entered into an agreement to terminate its manufacturing and supply agreement with Shire plc ( "Shire" ) related to VANTAS. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of VANTAS or a percentage of royalties and other consideration received by the Company relative to a sublicense of the Company's VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for the Company to pay Shire a total of \$5 million consisting of an immediate payment of \$1 million and the balance of \$4 million in three annual installments commencing in January 2009. The Company will capitalize its obligation at the net present value of the payments and amortize the asset to expense over the remaining life of the license agreement.

(ii) In April 2008, the Company entered into a License, Supply and Distribution Agreement with Orion Corporation ( "Orion" ) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries. VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark and the United Kingdom. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. The Company received a \$7 million up-front payment and could receive certain contingent payments related to approvals and sales thresholds aggregating up to \$14 million. Additionally, the Company has agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. The agreement expires in April 2023, subject to earlier termination by either party under certain customary conditions of breach. The Agreement will automatically renew for one-year periods at a time, subject to the right of either party to terminate the agreement at any time effective at the end of the initial 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party.

(iii) In April 2008, the holder of the Company's issued and outstanding 239,425 shares of Series B Convertible Preferred Stock and 5,000 shares of Series C Convertible Preferred Stock exercised its conversion rights and converted all shares of issued and outstanding preferred stock into 622,220 shares of the Company's Common Stock.

(iv) In April 2008, the Company received from Alkermes, Inc. a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005 between the Company and Alkermes relating to the development of an inhaled formulation of a pharmaceutical product that includes trospium chloride for the treatment of chronic obstructive pulmonary disease. Over the last several months the Company and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by the Company and Alkermes. The Company disputes Alkermes' position that this agreement has terminated and the Company intends to pursue vigorously all its rights and remedies under this agreement and applicable law. The Company owns or has an exclusive license to various know-how, and owns the IND, relating to the product that has been under development by the Company and Alkermes. The Company also has certain rights to joint intellectual property.

*M. Recent Accounting Pronouncements*

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements* ( "SFAS 157" ), which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. The Company is evaluating the implications of this standard.



**Table of Contents**

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is evaluating the implications of this standard.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is not permitted. The effect of applying the consensus will be prospective for new contracts entered into on or after that date. The Company is evaluating the implications of this standard.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* ( SFAS 141R ). SFAS 141R replaces SFAS 141, *Business Combinations* ( SFAS 141 ). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R will apply prospectively to business combinations for which the acquisition date is on or after the Company's fiscal year beginning October 1, 2009. While the Company has not yet evaluated this statement for the impact that SFAS 141R will have on its consolidated financial statements, the Company will be required to expense costs related to any acquisitions after September 30, 2009.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS 160 ). SFAS 160 amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The Company has not yet determined the impact that SFAS 160 will have on its consolidated financial statements. SFAS 160 is effective for the Company's fiscal year beginning October 1, 2009.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Note Regarding Forward Looking Statements**

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), SANCTURA XR® (once-daily SANCTURA), NEBIDO® (testosterone undecanoate), VANTAS® (histrelin implant for prostate cancer) and SUPPRELIN® LA (histrelin implant for central precocious puberty); 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 refer 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, 2007. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS,



## **Table of Contents**

SUPPRELIN LA and VALSTAR ; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL<sup>®</sup> and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, and VALSTAR; product liability and insurance uncertainties; risks relating to the Redux-related litigation; need for additional funds and corporate partners, including for the development of our products; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; difficulties in managing our growth; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; 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, 2007. 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 specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Our approved products include SANCTURA<sup>®</sup> and SANCTURA XR for overactive bladder ( OAB ), co-promoted with our partner Allergan, Inc. ( Allergan ), VANTAS<sup>®</sup> for advanced prostate cancer, SUPPRELIN<sup>®</sup> LA for central precocious puberty ( CPP ), and DELATESTRYL<sup>®</sup> for the treatment of hypogonadism. We market our products through an approximately 100-person specialty sales force.

Our core urology and endocrinology portfolio contains multiple compounds in development in addition to our approved products. Our most advanced compounds are VALSTAR for bladder cancer, NEBIDO<sup>®</sup> for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, the octreotide implant for acromegaly and a biodegradable ureteral stent for the adjunctive treatment of kidney stones.

In addition to our core urology and endocrinology portfolio, there are multiple compounds outside of our core focus area which we either currently outlicense for development and commercialization, or intend to outlicense in the future. These compounds include pagoclone for stuttering, ALKS 27 for chronic obstructive pulmonary disease ( COPD ) which we have been jointly developing with Alkermes, Inc. ( Alkermes ), aminocandin for systemic fungal infections for which we licensed worldwide rights to Novoxel S.A. ( Novoxel ) and IP 751 for pain and inflammation for which we licensed worldwide rights to Cervelo Pharmaceuticals, Inc. ( Cervelo ).

On April 18, 2007, we acquired Valera Pharmaceuticals, Inc., ( Valera ) a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products (the Valera Acquisition ). The Valera Acquisition was accounted for under the purchase method of accounting and the results of operations of Valera have been included in our consolidated results from the acquisition date.

### **Recent Product Developments**

#### **VANTAS**

In April 2008, we entered into an agreement to terminate our manufacturing and supply agreement with Shire plc ( Shire ) related to VANTAS. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of VANTAS or a percentage of royalties and other consideration received by us relative to a sublicense of our VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for us to pay Shire a total of \$5 million consisting of an immediate payment of \$1 million and the balance of \$4 million in three annual installments commencing in January 2009. We will capitalize our obligation at the net present value of the payments and amortize the asset to expense over the remaining life of the license agreement.

In April 2008, we entered into a License, Supply and Distribution Agreement with Orion Corporation ( Orion ) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries. VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark and the United Kingdom. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. We received a \$7 million up-front payment and could receive certain contingent payments related to approvals and sales thresholds aggregating up to \$14 million. Additionally, we have agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009.





## Table of Contents

### SANCTURA XR

In September 2007, we entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. ( Esprit ), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement ). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, we received an up-front license fee, partially creditable by Allergan against future payments to us, of \$25 million, and approximately \$8 million as payment of the supply price for future deliveries of SANCTURA XR subject to purchase orders issued by Allergan. The Allergan Agreement also grants us the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately \$123 million over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. In addition, we will receive approximately \$9 million in annual sales force subsidy for fiscal year 2008 which can be extended for up to six months at our option. Third-party royalties paid by us as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will be reimbursed to us. We will also manufacture and supply SANCTURA XR through June 30, 2008, and SANCTURA through September 30, 2012, to Allergan at cost. We may also receive a long-term commercialization milestone payment of \$20 million related to generic competition. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR, which occurred in January 2008, or the date of the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

Collectively through March 31, 2008 and pursuant to all agreements between us and PLIVA d.d. ( PLIVA ), Esprit and Allergan, we have received approximately \$338 million in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to our marketing partners at our cost to manufacture.

### NEBIDO

In January 2008, we announced the final results of an additional Phase III pharmacokinetic trial for NEBIDO. The data from the trial showed that NEBIDO met its primary endpoints, including a responder analysis based on an average testosterone concentration during the steady state dosing interval and an outlier analysis based on the maximum testosterone concentration during the steady state closing interval. In addition, the drug was well-tolerated. The NDA for NEBIDO was submitted to the FDA by us on August 28, 2007. The NDA was accepted for review and the FDA Prescription Drug User Fee Act (PDUFA) target action date is June 27, 2008.

### VALSTAR

In April 2007, we submitted a Supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce VALSTAR. VALSTAR, originally approved by the FDA in 1998, is a sterile solution for intravesical (bladder) instillation of valrubicin, a chemotherapeutic anthracycline derivative and is the only product currently approved by the FDA for therapy of Bacillus Calmette-Guerin (BCG) -refractory carcinoma *in situ* (CIS) of the urinary bladder. VALSTAR is used in BCG-refractory bladder cancer patients who are not candidates for surgical bladder removal (cystectomy).

In August 2007 we received an approvable letter from the FDA for VALSTAR asking for clarification regarding manufacturing validation protocols and additional data on the manufacturing process which was promptly provided. In December 2007, based on the FDA's subsequent inspection of our third-party manufacturing facility, we received a non-approvable letter from the FDA. We are working with the FDA and our third-party manufacturer to bring the manufacturing facility into compliance with U.S. current Good Manufacturing Practices ( cGMP ). We anticipate resolving these issues during the first half of calendar 2008.

### IP 751

In October 2007, we licensed our worldwide rights to IP 751 to Cervelo and received an upfront payment of \$1,000,000. This revenue was deferred as of March 31, 2008 pending finalization of transfer of certain Cervelo know-how. The revenue will be recognized after all contractual obligations have been fulfilled, which is expected to occur in the three month period ending June 30, 2008. In addition, we could receive further payments based on regulatory and, if approved for marketing, commercial achievements aggregating approximately \$37 million, and royalties based upon net sales. Cervelo is responsible for all future development, manufacturing, marketing and financial obligations relating to IP 751. This agreement will terminate ten years after first commercial sale on a country-by-country basis and may be terminated by either party under certain customary conditions of breach and by Cervelo upon six months notice to us.



---

## **Table of Contents**

### **PRO 2000**

In February 2008, we were advised by the United Kingdom's Medical Research Council (MRC) that after review of data from the Phase III clinical trial of PRO 2000, our candidate vaginal microbicide for HIV prevention, the Independent Data Monitoring Committee (IDMC) has recommended that the low-dose arm (0.5%) continue to be tested for safety and effectiveness in the trial. The IDMC, a group of independent experts providing oversight to the MDP 301 trial, also recommended the high-dose arm (2.0%) be closed as there is no more than a small chance of the high dose showing protection against HIV infection compared to placebo gel. The trial is sponsored by the MRC and conducted by the Microbicides Development Programme, an international partnership of researchers established to develop microbicides for the prevention of HIV transmission. The 0.5% dose of PRO 2000 is also being tested for safety and effectiveness in an additional Phase III trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The NIAID trial, which has completed enrollment, is expected to be completed this summer.

### **ALKS 27**

On April 28, 2008, we received from Alkermes, Inc. a letter purporting to terminate the Feasibility Agreement dated as of February 4, 2005 between us and Alkermes relating to the development of an inhaled formulation of a pharmaceutical product that includes tropium chloride for the treatment of chronic obstructive pulmonary disease. Over the last several months we and Alkermes have been engaged in discussions with several third parties relating to the further development and commercialization of this product and with each other to provide for further development by us and Alkermes. We dispute Alkermes' position that this agreement has terminated and we intend to pursue vigorously all its rights and remedies under this agreement and applicable law. We own or have an exclusive license to various know-how, and own the IND, relating to the product that has been under development by us and Alkermes. We also have certain rights to joint intellectual property.

### **Other Recent Developments**

In March 2008, we announced that Glenn L. Cooper, M.D. plans to retire as Indevus' Chief Executive Officer and Chairman of the Board of Directors by September 1, 2008. Dr. Cooper plans to serve as our advisor for twelve months thereafter.

### **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 could differ from these estimates.

#### *Goodwill and Other Intangible Assets*

Our intangible assets consist of goodwill, VANTAS and our patented HYDRON® Polymer Technology. The HYDRON Polymer Technology is a proprietary, subcutaneous, retrievable, non-biodegradable, hydrogel reservoir-based drug delivery process involving a device designed to be inserted under a patient's skin allowing the release of drugs continuously, at even, controlled rates for periods up to twelve months (the HYDRON Technology). SFAS 142, *Goodwill and Other Intangible Assets*, requires that periodic tests of goodwill for impairment be performed and that the other intangibles be amortized over their useful lives unless those lives are determined to be indefinite. SFAS 142 requires that goodwill be tested for impairment under a two-step impairment process at least annually or more frequently whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. We did not record any impairment charges during the three or six month periods ended March 31, 2008.

We amortize the carrying value of the VANTAS and the HYDRON Technology assets using the straight-line method over useful lives of 14 years for VANTAS and 17 years for the HYDRON Technology. Annual amortization expense is expected to be approximately \$2 million. For the three and six months ended March 31, 2008, we recognized \$497,000 and \$993,000, respectively of amortization expense.

#### *Revenue Recognition Policy*

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

*Revenue Recognition:* We classify all revenue as product revenue or contract and license fee revenue. Any consideration received in advance of revenue recognition is recorded as deferred revenue. Product revenue consists primarily of revenues from sales of products, royalties and reimbursements for royalties owed by us. Product sales are generally recognized as revenue upon the later of shipment or title transfer to our customers. Sales of VANTAS and DELATESTRYL are recorded net of reserves for returns, rebates and allowances. For SUPPRELIN LA, where chargebacks, insurance reimbursement or refunds cannot be reasonably estimated, revenue is deferred until such amounts are known and recorded as product revenue net of reserves for rebates and allowances. Until October 16, 2007, the effective date of the Amended and

---

**Table of Contents**

Restated License, Commercialization and Supply Agreement with Esprit Pharmaceuticals Inc., which was simultaneously acquired by Allergan, Inc., (the Allergan Agreement ), we recorded sales of SANCTURA to our marketing partner as product sales. Subsequent to the Allergan Agreement, we determined that the arrangement represented a single unit of accounting and began aggregating all of the proceeds from sales of SANCTURA and SANCTURA XR with all of the other consideration received from Allergan, recording it all as deferred revenue and recognizing it as contract and license fee revenue using the appropriate revenue recognition model.

Royalty revenue consists of payments received from licensees for a portion of the sales proceeds from products that utilize our licensed technologies. Royalties are generally reported to us in a royalty report on a specified periodic basis and recognized in the period in which the sales of the product or technology on which the royalties are based occurred. If the royalty report for such period is received subsequent to the time when 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, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments. Our business strategy includes entering into collaborative license, development, supply and 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 resulting from the achievement of certain milestones and royalties on net product sales.

Many of our agreements contain multiple elements and require evaluation 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 obligations, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered elements in the arrangement. In the case of an arrangement where it is determined that there is a single unit of accounting, all cash flows from the arrangement are aggregated and recognized as revenue over the term of the arrangement as we complete our performance obligations. We record such revenue as contract and license fee revenue.

Certain multiple element arrangements include provisions for us to participate on various committees, such as steering committees, development committees, and commercialization committees. We evaluate the facts and circumstances of the arrangement to determine if our participation is protective of our interests or if it constitutes a deliverable to be included in our evaluation of the arrangement under EITF 00-21. Additionally, pursuant to the guidance in Securities and Exchange Commission Bulletin ( SAB ) No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected period of the arrangements during which we have continuing performance obligations.

We have elected to use the proportional performance model to determine recognition of revenue related to multiple element arrangements determined to be single units of accounting where we have continuing performance obligations and can estimate the completion of our earnings process. Under the Allergan Agreement, because we cannot determine the total amount of expected revenue or the pattern by which we will complete our obligations, all consideration is recognized as contract and license fee revenue using the Contingency-Adjusted Performance Model ( CAPM ). Under this model, when a portion of the consideration under the arrangement 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 Allergan Agreement to the time the milestone is earned over the estimated performance period of the Allergan Agreement. Thereafter, the remaining portion of the consideration is recognized on a straight-line basis over the remaining estimated performance period of the Allergan Agreement. In other multiple element arrangements where we can estimate our expected revenue and measure our completion of the earnings process, we utilize the proportional performance model.

In multiple element arrangements, where we have separate units of accounting, revenues from milestone payments related to arrangements under which we have no 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.

**Table of Contents***Expected Terms of the Agreements regarding SANCTURA and SANCTURA XR and Deferred Revenue*

We executed the Allergan Agreement effective on October 16, 2007, the terms and conditions of which required an assessment of the expected term over which we have continuing performance obligations. We assessed the Allergan Agreement pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Based on this assessment, we determined that we had multiple deliverables, however the delivered elements did not have stand-alone value and there was no objective, reliable evidence of fair value for the undelivered elements. Thus, we concluded that the arrangement represented a single unit of accounting. Our obligations are expected to cease no later than September 30, 2012. Accordingly, commencing on the effective date of the Allergan Agreement, we commenced recognizing the deferred revenue balances that existed on the effective date, as well as the initial license payment of \$25 million, over the approximately 5-year performance period. All future payments received from Allergan during the performance period, including royalties, sales force reimbursement and product revenue will be amortized using the CAPM. All payments received after the performance period will be recognized as revenue when earned.

Prior to the October 16, 2007 effective date of the Allergan Agreement, we were recording the initial and milestone payments received from PLIVA and Esprit as deferred revenue and recognizing such payments as revenue using the CAPM over the estimated twelve year term of the original agreement with PLIVA, commencing on the date such payments were received.

After consideration of the estimated performance periods as noted above, we amortized \$10,336,000 and \$5,062,000 of deferred revenue into contract and license fee revenue during the three months ended March 31, 2008 and 2007, respectively. We amortized \$18,910,000 and \$10,708,000 of deferred revenue into contract and license fee revenue during the six months ended March 31, 2008 and 2007, respectively. The balance of deferred revenue related to the Allergan Agreement at March 31, 2008 was \$182,499,000.

In November 2006, we entered into several agreements with Madaus GmbH ( Madaus ) relative to SANCTURA and SANCTURA XR in certain non U.S. territories (the Madaus Agreements ). The Madaus Agreements have been combined for accounting purposes and we evaluated the multiple deliverables in accordance with the provisions of EITF 00-21. We were unable to demonstrate that the delivered items had stand alone value or that the undelivered elements had verifiable objective evidence of fair value, and thus we concluded that the arrangement represented a single unit of accounting. Initially, upon execution of the Madaus Agreements, we were unable to determine the term of our obligation to provide future know-how to Madaus. Subsequent to the Allergan Agreement, we reevaluated this performance obligation and determined that it was analogous to a performance obligation we have to provide know-how to Allergan. Per the Allergan Agreement, our know-how obligations are expected to cease no later than September 30, 2012. Accordingly, we will recognize all payments received from Madaus through September 30, 2012 using the CAPM and will reflect the recognition of such payments as contract and license fee revenue over the approximately 6-year performance period. All payments received after the approximately 6-year performance period will be recognized as revenue when earned. In addition, we have evaluated payments to be made by us to Madaus under the Madaus Agreements in accordance with the provisions of EITF 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products) , and have determined that we are receiving a separable benefit for each payment and each benefit has objective evidence of fair value.

*Redux-Related Liabilities*

At March 31, 2008, we have an accrued liability of approximately \$500,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at March 31, 2008. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

*Insurance Claim Receivable*

As of March 31, 2008, we had an outstanding insurance claim of approximately \$3,300,000, consisting of payments made by us to the group of law firms defending us in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. 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 ). During the three month period ended

**Table of Contents**

March 31, 2008, we received a partial payment of \$400,000 from Reliance pertaining to this claim. 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 \$858,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately \$2,400,000 against the insurance claim on Reliance as of March 31, 2008 is a significant estimate reflecting management's judgment. To the extent we do not collect the insurance claim receivable of \$858,000 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.

*Cash, Cash Equivalents and Marketable Securities*

We invest available cash primarily in short-term bank deposits, money market funds, repurchase agreements, domestic and foreign commercial paper and government securities. Cash and cash equivalents include investments with maturities of three months or less at date of purchase. Marketable securities consist of investments purchased with maturities greater than three months and are classified as noncurrent if they mature one year or more beyond the balance sheet date and are not considered available to fund current operations. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income or loss until realized. The fair value of these securities is based on quoted market prices. At March 31, 2008 and September 30, 2007, we had no marketable securities.

*Inventory Capitalization Policy*

Inventories are stated at the lower of cost or market with cost determined under the first in, first out ( FIFO ) method. Included in inventory costs are materials, drug costs, direct labor and manufacturing overheads that include facility costs and indirect manufacturing costs. We expense costs related to inventory until such time as we receive approval from the FDA to market a product, at which time we commence capitalization of costs relating to that product.

*Accounting for Stock-Based Compensation*

We have several stock-based employee compensation plans. On October 1, 2005, we adopted SFAS 123R Accounting for Stock-Based Compensation ( SFAS 123R ). 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. We are required to make significant estimates related to SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended March 31, 2008 and 2007, we used a weighted-average expected stock-price volatility of 49.5% and 60.6%, respectively. For stock option grants issued to non-executives during the six months ended March 31, 2008 and 2007, we used a weighted-average expected stock-price volatility of 49.1% and 60.7%, respectively. For stock option grants to executives during the three months ended March 31, 2008 and 2007, we used a weighted average expected stock-price volatility of 52.9% and 64.0%, respectively. For stock option grants to executives during the six months ended March 31, 2008 and 2007, we used weighted average expected stock-price volatility ranges of 50.0% to 52.9% and 62.8% to 64.0%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. 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 months ended March 31, 2008 and 2007, we used a weighted-average expected option life assumption of 6.50 and 6.25, respectively, for non-executives and 8.0 years for executives. For stock option grants made during the six months ended March 31, 2008 and 2007, we used a weighted-average expected option life assumption of 6.47 years for non-executives and 8.0 years for executives. A shorter expected term would result in lower compensation expense.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

---

**Table of Contents****Results of Operations**

Our net loss increased \$5,467,000 to \$(17,906,000), or \$(0.23) per share, basic, in the three month period ended March 31, 2008 from \$(12,439,000), or \$(0.22) per share, basic, in the three month period ended March 31, 2007 and increased \$9,871,000 to \$(32,609,000), or \$(0.43) per share, basic, in the six month period ended March 31, 2008 from \$(22,738,000), or \$(0.41) per share, basic, in the six month period ended March 31, 2007. The increased net loss in the three and six months ended March 31, 2008 is primarily the result of increased sales and marketing expense related to NEBIDO and products obtained through our acquisition of Valera partially offset by increased gross margin from sales of VANTAS and SUPPRELIN LA and decreased research and development costs.

Total revenues increased \$6,419,000, or 57%, to \$17,643,000 in the three month period ended March 31, 2008 from \$11,224,000 in the three month period ended March 31, 2007 and increased \$9,667,000, or 40%, to \$34,042,000 in the six month period ended March 31, 2008 from \$24,375,000 in the six month period ended March 31, 2007.

Historically, product revenue included shipments of SANCTURA to our marketing partner Esprit, as well as royalty payments received from Esprit whereas amortization of deferred revenue from the upfront and milestone payments from Esprit resulting from our collaboration agreement was recorded in contract and license fee revenue. Management assessed the accounting model for the Allergan Agreement and determined that as of October 16, 2007, all payments received from Allergan under this new arrangement, including upfront fees, sales force payments, product sales and royalties, would be accounted for as a single unit of accounting and reflected as contract and license fee revenue in our income statement using the CAPM.

Product revenue increased \$3,754,000 or 109%, to \$7,209,000 in the three month period ended March 31, 2008 from \$3,455,000 in the three month period ended March 31, 2007 and increased \$5,795,000 or 67%, to \$14,507,000 in the six month period ended March 31, 2008 from \$8,712,000 in the six month period ended March 31, 2007. Included in revenue for the three and six month periods ended March 31, 2008 is \$3,583,000 and \$7,159,000, respectively of revenue resulting from the sales of VANTAS, and \$2,986,000 and \$5,247,000, respectively of revenue resulting from the sales of SUPPRELIN LA, both of which were obtained through our acquisition of Valera in April 2007. Included in revenue for the three and six month periods ended March 31, 2007 is \$2,461,000 and \$6,805,000 of revenue related to product and royalty revenue resulting from our prior collaboration with Esprit.

Contract and license fee revenues increased \$2,665,000 or 34%, to \$10,434,000 in the three month period ended March 31, 2008 from \$7,769,000 in the three month period ended March 31, 2007 and \$3,872,000 or 25%, to \$19,535,000 in the six month period ended March 31, 2008 from \$15,663,000 in the six month period ended March 31, 2007. The increase in contract and license fee revenue is primarily related to the Esprit and Allergan Agreements and is due primarily to the receipt of a \$25 million milestone payment from Allergan in October 2007 which, along with the previously deferred revenue, is now being recognized over a five year CAPM which replaces the previous twelve year CAPM applied through October 16, 2007. In addition, product and royalty payments resulting from the Allergan collaboration are accounted for under the CAPM commencing as of the October 16, 2007 effective date of the amended collaboration. Such revenues had previously been reflected as product revenues when the product was shipped and when the royalties were due and payable from Esprit. As of March 31, 2008, we have approximately \$182,499,000 of deferred revenue related to the Allergan Agreement which is expected to be recognized under CAPM through September 30, 2012.

Cost of revenue increased \$5,138,000, or 403%, to \$6,412,000 in the three month period ended March 31, 2008 from \$1,274,000 in the three month period ended March 31, 2007 and \$6,717,000, or 121%, to \$12,267,000 in the six month period ended March 31, 2008 from \$5,550,000 in the six month period ended March 31, 2007. Included in this increase are costs of \$2,827,000 and \$5,400,000 related to sales of VANTAS for the three and six month periods ended March 31, 2008, respectively. Costs associated with sales of SANCTURA and SANCTURA XR increased \$2,415,000 and \$2,340,000 for the three and six month periods ended March 31, 2008, respectively.

Research and development expense decreased \$3,019,000, or 33%, to \$6,253,000 in the three month period ended March 31, 2008 from \$9,272,000 in the three month period ended March 31, 2007 and \$6,546,000, or 34%, to \$12,645,000 in the six month period ended March 31, 2008 from \$19,191,000 in the six month period ended March 31, 2007. External product development costs related to SANCTURA and SANCTURA XR decreased approximately \$3,223,000 in the three month period ended March 31, 2008 and \$7,351,000 in the six month period ended March 31, 2008 because the product was approved in August 2007. External product development costs for NEBIDO decreased approximately \$1,583,000 in the three month period ended March 31, 2008 and \$1,470,000 in the six month period ended March 31, 2008 due to decreased clinical costs primarily due to decreased investigator fees and laboratory services. Partially offsetting these decreased external development costs during the three months ended March 31, 2008 were increased external product development costs of \$2,128,000 incurred for products obtained through our purchase of Valera, including \$1,558,000 for VALSTAR and the





**Table of Contents**

octreotide and naltrexone implants. During the six months ended March 31, 2008, increased external product developments costs of \$3,056,000 were incurred for products obtained through our purchase of Valera, including \$2,037,000 for VALSTAR and the octreotide and naltrexone implants.

Marketing, general and administrative expense increased \$8,589,000, or 68%, to \$21,276,000 in the three month period ended March 31, 2008 from \$12,687,000 in the three month period ended March 31, 2007 and \$17,352,000, or 80%, to \$39,042,000 in the six month period ended March 31, 2008 from \$21,690,000 in the six month period ended March 31, 2007.

Marketing expense increased \$5,457,000, or 68%, to \$13,432,000 in the three month period ended March 31, 2008 from \$7,975,000 in the three month period ended March 31, 2007 and \$11,654,000, or 91%, to \$24,449,000 in the six month period ended March 31, 2008 from \$12,795,000 in the six month period ended March 31, 2007. This increase is primarily the result of advertising and other marketing expense for VANTAS and SUPPRELIN LA, pre-launch costs related to NEBIDO and VALSTAR and additional sales force costs related to Valera's sales force and products.

General and administrative expense increased \$3,132,000, or 66%, to \$7,844,000 in the three month period ended March 31, 2008 from \$4,712,000 in the three month period ended March 31, 2007 and \$5,698,000, or 64%, to \$14,593,000 in the six month period ended March 31, 2008 from \$8,895,000 in the six month period ended March 31, 2007. Included in the general and administrative expense for the three and six month periods ended March 31, 2008 is increased headcount-related expense of approximately \$834,000 and \$1,660,000, respectively, increased recruiting costs of approximately \$482,000 and \$536,000, respectively and increased legal and professional services fees of approximately \$377,000 and \$965,000, respectively. Increased rent expense and other related costs of \$116,000 and \$309,000 for the three and six month periods ended March 31, 2008 is a result of our acquisition of Valera. Also included in general and administrative expense for the six month period ended March 31, 2008 is a charge of \$442,000 related to a sublease of a portion of our Cranbury facilities.

In connection with our acquisition of Valera, we acquired certain intangible assets, including VANTAS and the HYDRON Technology. We have recorded amortization expense of \$497,000 and \$993,000 during the three month and six month periods ended March 31, 2008, respectively, related to these intangible assets. The annual amortization of these intangible assets is expected to be approximately \$2,000,000. The estimated life of these intangible assets is fourteen to seventeen years.

Investment income decreased \$213,000, or 25%, to \$650,000 in the three month period ended March 31, 2008 from \$863,000 in the three month period ended March 31, 2007 and \$134,000, or 7%, to \$1,769,000 in the six month period ended March 31, 2008 from \$1,903,000 in the six month period ended March 31, 2007. The decrease in investment income in the three and six month periods ended March 31, 2008 is the result of lower average interest rates and lower average funds available for investment.

Interest expense relates to our \$71,925,000 of 6.25% Convertible Senior Notes due July 2009 and \$75,000 of 6.25% Convertible Senior Notes due July 2008 (the Convertible Notes). Interest expense of approximately \$1,761,000 in the three months ended March 31, 2008 includes \$1,125,000 of interest to be paid, approximately \$83,000 of amortization of original debt issuance costs, and approximately \$548,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value. Interest expense of approximately \$3,473,000 in the six months ended March 31, 2008 includes \$2,250,000 of interest to be paid, approximately \$165,000 of amortization of original debt issuance costs, and approximately \$1,051,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value. Total interest expense in fiscal 2008 is expected to be approximately \$6,978,000, and will include approximately \$2,150,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value.

**Liquidity and Capital Resources**

**Cash, Cash Equivalents and Marketable Securities**

At March 31, 2008 we had consolidated cash and cash equivalents of \$60,765,000 compared to consolidated cash and cash equivalents of \$71,142,000 at September 30, 2007. This decrease of \$10,377,000 is primarily the result of net cash used in operating activities of \$10,567,000 (see Analysis of Cash Flows).

We are continuing to invest substantial amounts in the ongoing development of our product candidates and sales activities related to our marketed products SANCTURA and SANCTURA XR, SUPPRELIN LA and VANTAS. In fiscal 2008, we expect to continue investing in pre-marketing activities related to NEBIDO and, if the product is approved, launch and marketing activities. If approved by the FDA, we also expect to invest in launch and marketing activities related to VALSTAR. We are continuing to invest in the development of NEBIDO. We may purchase inventory of NEBIDO prior to FDA approval in order to be ready to launch NEBIDO soon after approval. We believe our current and expected cash resources are sufficient to fund our operations through approximately the middle of the first calendar quarter of 2009. We



---

**Table of Contents**

will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to us. The failure to raise such funds would result in the need to significantly curtail our marketing activities and delay development efforts, which would have a material adverse effect on us.

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.

We have \$71,925,000 of our 6.25% Convertible Senior Notes outstanding which are due in July 2009. If these notes do not convert into common stock by July 15, 2009, we will be required to redeem these notes for cash.

There remain 1,950,000 shares issuable pursuant to a shelf registration statement on Form S-3 we filed with the SEC in December 2005. The registration statement remains effective and the 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.

In April 2008, the holder of our issued and outstanding 239,425 shares of Series B Convertible Preferred Stock and 5,000 shares of Series C Convertible Preferred Stock exercised its conversion rights and converted all shares of issued and outstanding preferred stock into 622,220 shares of our Common Stock.

**Product Development**

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 March 31, 2008 on our core development products for which an NDA has not been filed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: \$24,000,000 for PRO 2000 and \$4,000,000 for the octreotide implant. We have not included compounds in development for which we do not expect to incur additional material research and development costs. 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 the above 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 March 31, 2008 through the preparation of an NDA for our core development compounds as follows: approximately \$14,000,000 for PRO 2000 and \$13,000,000 for the octreotide implant. 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. When we acquired Valera on April 18, 2007, the following products were in development and unapproved: SUPPRELIN LA, the octreotide implant and the biodegradable ureteral stent. SUPPRELIN LA was approved in May 2007 and the other products are continuing under development. We are currently considering strategic partners for future development and commercialization of PRO 2000 and evaluating commercialization options for pegoclone in parallel with our ongoing development program and preliminary market development activities.

---

**Table of Contents**

Analysis of Cash Flows

Net cash used in operating activities

For the six months ended March 31, 2008, our primary source of funds was related to our agreements with Allergan and Esprit. On the effective date of the Allergan Agreement, we received an up-front fee of \$25 million and a payment of the supply price for future deliveries of SANCTURA XR of \$8 million. Cash was expended primarily in the normal operations of our business by the various functions as represented in the statement of operations. Net cash used in operating activities in the six month period ended March 31, 2008 of \$10,567,000 consisted primarily of (i) the net loss of \$32,609,000, (ii) a decrease in accrued expenses and other liabilities of \$6,690,000, (iii) an increase in inventory balances of \$3,742,000 related to the purchase of trospium active pharmaceutical ingredient, and (iv) an increase in accounts receivable of \$4,488,000 primarily due to increased sales of SUPPRELIN LA and increased amounts due from Allergan, partially offset by (i) a \$26,001,000 increase in deferred revenue primarily due to payments from Allergan, net of amortization, and (ii) \$6,931,000 of noncash charges for stock-based compensation, lease abandonment, depreciation and amortization and note discount amortization.

For the six months ended March 31, 2007, net cash used in operating activities of \$14,623,000 consisted primarily of the net loss of \$22,738,000. Additionally contributing to cash used in operating activities was a \$1,153,000 increase in accounts receivable and a \$1,001,000 decrease in accounts payable. The increase in accounts receivable was primarily due to the timing of collection of the monthly sales force receivable due from Esprit. The decrease in accounts payable was primarily due to the timing of when we received vendor invoices and our payments against those invoices. Partially offsetting these uses of cash in operating activities was noncash stock-based compensation of \$2,645,000, establishment of a noncash charge for excess DELATESTRYL inventory of approximately \$1,100,000 and an increase in accrued expenses and other liabilities of \$3,582,000 primarily related to an increase in accrued R&D contracts.

Net cash used in operating activities of \$10,567,000 for the six months ended March 31, 2008 decreased \$4,056,000 from \$14,623,000 for the six months ended March 31, 2007. Net loss increased \$9,871,000 for the six months ended March 31, 2008 from the six months ended March 31, 2007 as described in Results of Operations. Also, the change in deferred revenue between the six months ended March 31, 2008 and the six months ended March 31, 2007 resulted in an improvement in cash used in operations of \$25,226,000 as there was an increase in deferred revenue from receipts from Allergan in the first two quarters of fiscal 2008. In addition, pursuant to the Allergan Agreement, all payments received from Allergan, including upfront fees, sales force payments, product sales and royalties, are now accounted for as a single unit of accounting and are reflected as contract and license fee revenue in our income statement using the CAPM, which increased our deferred revenue balance over the six months ended March 31, 2007.

Net cash (used in) provided by investing activities

For the six months ended March 31, 2008, net cash used in investing activities of \$2,191,000 resulted from purchases of property, plant and equipment.

For the six months ended March 31, 2007, net cash provided by investing activities of \$2,657,000 was primarily comprised of maturities and sales of marketable securities of \$5,956,000, offset by prepaid Valera acquisition costs of \$3,113,000.

Net cash (used in) provided by investing activities of (\$2,191,000) for the six months ended March 31, 2008 decreased \$4,848,000 from \$2,657,000 for the six months ended March 31, 2007.

Net cash provided by financing activities

For the six months ended March 31, 2008, net cash provided by financing activities of \$2,381,000 resulted from common stock issued from exercises of stock options and employee participation in our employee stock purchase plan. We cannot predict if or when stock options will be exercised in the future.

For the six months ended March 31, 2007, net cash provided by financing activities of \$806,000 resulted from common stock issued from employee exercises of stock options and employee participation in our employee stock purchase plan.

Net cash provided by financing activities of \$2,381,000 for the six months ended March 31, 2008 increased \$1,575,000 from \$806,000 for the six months ended March 31, 2007 due primarily to exercises of stock options.

**Recent Accounting Pronouncements**

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

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements*, ( SFAS 157 ) which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard

**Table of Contents**

provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. We are evaluating the implications of this standard.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are evaluating the implications of this standard.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. This consensus is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier adoption is not permitted. The effect of applying the consensus will be prospective for new contracts entered into on or after that date. We are evaluating the implications of this standard.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* ( SFAS 141R ). SFAS 141R replaces SFAS 141, *Business Combinations* ( SFAS 141 ). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R will apply prospectively to business combinations for which the acquisition date is on or after our fiscal year beginning October 1, 2009. While we have not yet evaluated this statement for the impact that SFAS 141R will have on our consolidated financial statements, we will be required to expense costs related to any acquisitions after September 30, 2009.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS 160 ). SFAS 160 amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. We have not yet determined the impact that SFAS 160 will have on our consolidated financial statements. SFAS 160 is effective for our fiscal year beginning October 1, 2009.

**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





---

## **Table of Contents**

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 \$42.50. 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 \$36.25. 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 March 31, 2008, 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 March 31, 2008 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

#### **Changes in Internal Control Over Financial Reporting**

Subject to the qualifications set forth below, 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 March 31, 2008 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 (formerly American Home Products Corporation), 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. After the withdrawal of Redux, we were named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purported 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.

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth pursuant to which Wyeth agreed to indemnify us against certain classes of product liability cases filed against us involving 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 agreed to fund all future legal costs related to our defense of Redux-related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure.

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.

On January 18, 2005, Wyeth announced that they had developed a proposed process by which large numbers of cases involving claimants, who opted out of Wyeth's national class action settlement and who have named both Wyeth and Indevus as defendants, might be negotiated and settled. Since that date a significant number of cases in which Indevus has been named as a defendant have been dismissed or resolved.

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

*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

**Table of Contents**

management time and resources to these legal actions. In the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against us and our officers and directors, our business, financial condition and results of operations could be materially adversely affected. The uncertainties and costs associated with these legal actions have had, and may continue to have an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, or to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

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

Our annual meeting of stockholders was held on March 11, 2008. The purpose of the annual meeting was to consider and vote upon the proposals set forth below:

1. To elect seven members of our board of directors to serve until the 2009 annual meeting of stockholders or until their successors are elected and qualified. The following directors were elected at the annual meeting for a one-year term by the votes indicated: Glenn L. Cooper, M.D., 60,361,626 for, 3,129,875 withheld; Andrew Ferrara, 60,583,708 for, 2,907,793 withheld; James C. Gale, 59,890,655 for, 3,600,846 withheld; Michael E. Hanson, 60,419,133 for, 3,072,368 withheld; Stephen C. McCluski, 60,418,784 for, 3,027,717 withheld; Cheryl P. Morley, 60,443,043 for, 3,048,458 withheld; and Malcolm Morville, Ph.D., 60,490,517 for, 3,000,984 withheld; and

2. To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm. The proposal was ratified at the annual meeting by a vote of 60,684,234 for, 2,294,529 against, 45,449 abstaining, and no broker non-votes.

Additional information with respect to the proposals above is included in the proxy statement filed as part of the Definitive Proxy Statement filed by us with the Securities and Exchange Commission on January 24, 2008.

**Table of Contents**

**Item 6. Exhibits**

(a) Exhibits

- 3.1 Restated Certificate of Incorporation, as amended (1)
- 3.2 By-Laws Certificate of Amendment of Restated Certificate of Incorporation, as amended (2)
- 10.1 Executive Retirement Agreement by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated March 3, 2008. (\*) (3)
- 10.2 Grant of Deferred Stock Units on March 11, 2008 to each non-employee member of the Board of Directors of Indevus (\*) (4)
- 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 (4)
- 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 (4)
- 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 (4)
- 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 (4)

(\*) Management contract or compensatory plan or arrangement

- (1) Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K filed with the SEC on December 14, 2005 and Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2007.
- (2) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 7, 2007.
- (3) Incorporated by reference to the Company's Form 8-K filed with the SEC on March 7, 2008.
- (4) Filed with this report.

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC.

Date: May 2, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: May 2, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: May 2, 2008

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