

INDEVUS PHARMACEUTICALS INC

Form 10-Q

February 04, 2009

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended December 31, 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)

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**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 February 3, 2009**  
**78,681,400 shares**

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

	<b>December 31, 2008</b>	<b>September 30, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 125,555	\$ 131,306
Restricted cash	5,346	5,150
Accounts receivable, net	16,701	14,512
Inventories, net	4,977	6,179
Prepaid and other current assets	6,177	4,998
Total current assets	158,756	162,145
Property, plant and equipment, net	8,824	9,224
Restricted cash	3,199	4,850
Goodwill	48,244	48,244
Intangible assets, net	30,218	30,855
Other assets	7,055	7,684
Total assets	\$ 256,296	\$ 263,002
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$ 6,046	\$ 7,338
Accrued expenses	19,593	16,116
Accrued interest	4,686	2,582
Deferred revenue	49,399	46,766
Convertible notes	70,736	70,187
Total current liabilities	150,460	142,989
Non-recourse notes	105,000	105,000
Deferred revenue	134,913	142,249
Other	1,819	2,950
<b>STOCKHOLDERS DEFICIT</b>		
Common Stock, \$.001 par value, 200,000,000 shares authorized; 78,187,924 and 78,151,809 shares issued and outstanding at December 31, 2008 and September 30, 2008, respectively	78	78
Additional paid-in capital	513,664	511,788
Accumulated deficit	(649,638)	(642,052)
Total stockholders deficit	(135,896)	(130,186)
Total liabilities and stockholders deficit	\$ 256,296	\$ 263,002

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



**Table of Contents****INDEVUS PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****For the three months ended December 31, 2008 and 2007****(Unaudited)****(Amounts in thousands except per share data)**

	<b>Three months ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>		
Product revenue	\$ 13,061	\$ 7,298
Contract and license fees	13,336	9,100
<b>Total revenues</b>	<b>26,397</b>	<b>16,398</b>
<b>Costs and expenses:</b>		
Cost of revenues	6,534	5,855
Research and development	5,188	6,391
Marketing, general and administrative	15,948	17,766
Amortization of intangible assets	637	497
<b>Total costs and expenses</b>	<b>28,307</b>	<b>30,509</b>
<b>Loss from operations</b>	<b>(1,910)</b>	<b>(14,111)</b>
Investment income	596	1,120
Interest expense	(6,272)	(1,712)
<b>Net loss</b>	<b>\$ (7,586)</b>	<b>\$ (14,703)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.10)</b>	<b>\$ (0.19)</b>
<b>Weighted average common shares outstanding, basic and diluted</b>	<b>77,616</b>	<b>76,307</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 three months ended December 31, 2008 and 2007****(Unaudited)****(Amounts in thousands)**

	<b>For the three months ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Cash flows from operating activities:		
Net loss	\$ (7,586)	\$ (14,703)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,303	983
Note discount amortization	802	583
Stock-based compensation	1,775	1,610
Lease abandonment		442
Changes in assets and liabilities:		
Accounts receivable	(2,189)	(3,177)
Inventories	1,202	(1,443)
Prepaid and other assets	(804)	(430)
Accounts payable	(1,291)	(1,799)
Accrued expenses and other liabilities	4,450	(2,279)
Deferred revenue	(4,702)	29,961
<b>Net cash (used in) provided by operating activities</b>	<b>(7,040)</b>	<b>9,748</b>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(267)	(451)
<b>Net cash (used in) investing activities</b>	<b>(267)</b>	<b>(451)</b>
Cash flows from financing activities:		
Restricted cash used for debt service	1,455	
Proceeds from exercise of stock options	101	1,861
<b>Net cash provided by financing activities</b>	<b>1,556</b>	<b>1,861</b>
<b>Net change in cash and cash equivalents</b>	<b>(5,751)</b>	<b>11,158</b>
Cash and cash equivalents at beginning of period	131,306	71,142
<b>Cash and cash equivalents at end of period</b>	<b>\$ 125,555</b>	<b>\$ 82,300</b>
Supplemental disclosures of cash flow information and noncash transactions:		
Cash paid for interest	\$ 3,220	\$

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

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**INDEVUS PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

*A. Basis of Presentation*

The consolidated interim financial statements included herein have been prepared by Indevus Pharmaceuticals, Inc. ( Indevus or the Company ) without audit, pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ( SEC ). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company. The unaudited consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Form 10-K for the fiscal year ended September 30, 2008.

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 SANCTURA and SANCTURA XR for overactive bladder ( OAB ), co-promoted with its partner Allergan, Inc. ( Allergan ), VANTAVA for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty ( CPP ), and DELATESTRYL 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 hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

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 pagocloner for stuttering for which we licensed to Teva Pharmaceutical Industries Ltd. ( Teva ), ALKS 27 for chronic obstructive pulmonary disease ( COPD ) which the Company has been jointly developing with Alkermes, Inc. ( Alkermes ), and aminocandin for systemic fungal infections for which the Company licensed worldwide rights to Novoxel S.A. ( Novoxel ).

*B. Tender Offer*

On January 5, 2009, the Company entered into a definitive Merger Agreement ( Merger Agreement ) under which Endo Pharmaceuticals Holdings Inc. ( Endo ), a Delaware corporation, and BTB Purchaser Inc. ( Purchaser ), a Delaware corporation and direct wholly-owned subsidiary of Endo, commenced a tender offer (the Offer ) to acquire 100 percent of the Company's outstanding shares for approximately \$370,000,000, or \$4.50 per share (less any required withholding taxes and without interest), in cash and contractual rights to receive up to an additional approximately \$267,000,000, or \$3.00 per share, in cash payable by Endo in the future upon achievement of certain milestones related to NEBIDO and the octreotide implant ( Contingent Cash Payments ). The transaction has been approved by the boards of directors of the Company and Endo.

The first Contingent Cash Payment relates to NEBIDO and is payable as follows: (i) \$2.00 per share if NEBIDO is approved by the FDA, within three (3) years of the closing of the tender offer, by the FDA for marketing and sale without certain restrictive labeling, or (ii) up to two potential payments in the event that NEBIDO is approved by the FDA with certain restrictive labeling, comprised of: (a) \$1.00 per share upon such approval, if FDA approval is obtained within three (3) years of the closing of the tender offer and (b) an additional \$1.00 per share following the achievement of a certain sales threshold milestone during the first five (5) years from the date of the first commercial sale of NEBIDO.

The second Contingent Cash Payment relates to the octreotide implant and consists of \$1.00 per share to be paid in the event that, within four (4) years of the closing of the tender offer, octreotide is approved by the FDA for marketing and sale for the treatment of acromegaly or carcinoid syndrome.

Pending at least a majority of the outstanding shares of common stock of the Company on a fully diluted basis being tendered in the Offer, as well as satisfaction of other customary closing conditions, and subject to certain extension rights, the tender offer is scheduled to close in the second fiscal quarter of 2009.

*C. Accounting Policies*



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*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

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recognized as revenue upon the later of shipment or title transfer to the Company's customers. Sales of SUPPRELIN LA, VANTAS and DELATESTRYL are recorded net of reserves for returns, rebates and allowances. 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, (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 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 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.

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, and since October 2007, sales of SANCTURA product. 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 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



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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 December 31, 2008 and September 30, 2008, the Company had no marketable securities.

*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 December 31, 2008 and 2007, the Company used a weighted-average expected stock-price volatility of 86.5% and 46%, respectively. There were no stock options grants issued to executives during the three months ended December 31, 2008. For stock option grants issued to executives during the three months ended December 31, 2007, the Company used a weighted-average expected stock-price volatility of 50%. 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 to non-executives during the three months ended December 31, 2008 and 2007, the Company used a weighted-average expected option life assumption of 6.0 and 6.25 years, respectively. For stock option grants made to executives during the three months ended December 31, 2007, the Company used a weighted-average expected option life assumption of 8.0 years.

During the three months ended December 31, 2008, the Board of Directors approved modifications to extend the term of certain outstanding fully vested options and the Company recorded \$448,000 of noncash compensation expense related to these modifications. Pursuant to SFAS 123R, the Company is required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of stock options.

The Company has also granted restricted stock units and performance stock awards. The value of these awards is being expensed over the respective vesting period. For the three months ended December 31, 2008 and 2007, the Company recognized \$299,000 and \$305,000, respectively, in stock-based compensation related to these restricted stock units and performance stock awards.

Inclusive of the above stock-based compensation, during the three months ended December 31, 2008 and 2007, the Company recognized \$1,775,000 and \$1,610,000, respectively, in total stock-based compensation.

*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.

### *D. 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. In addition, the Company's Convertible Notes 2009 of \$71,925,000 will become due in July

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2009. The Company believes its current and expected cash resources are sufficient to fund its operations into approximately the first calendar quarter of 2010. The Company will need to obtain

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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 operating activities and delay development efforts, which would have a material adverse effect on the Company.

*E. Goodwill and Intangible Assets*

The carrying amount of goodwill is \$48,244,000 at December 31, 2008 and was recorded in connection with the Valera Acquisition in April 2007. The Company did not incur any triggering events within the three months ended December 31, 2008 that would warrant an interim goodwill impairment assessment.

The Company's net intangible assets at December 31, 2008 totaled \$30,218,000. Approximately \$26,707,000 of the Company's net intangible assets related to VANTAS and the Hydron Polymer Technology, acquired in connection with the Valera Acquisition in April 2007 and approximately \$3,511,000 related to the purchase of the Shire license in April 2008.

Amortization expense for intangible assets totaled approximately \$637,000 and \$497,000 during the three months ended December 31, 2008 and 2007, respectively. The annual amortization expense for each of the next five years for the intangible assets is expected to be approximately \$2,500,000.

*F. 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:

	December 31, 2008	September 30, 2008
Raw materials	\$ 776,000	\$ 1,424,000
Work in process	3,052,000	3,215,000
Finished goods	1,149,000	1,540,000
	\$ 4,977,000	\$ 6,179,000

All of the Company's inventories at the balance sheet date relate to commercially approved products: SANCTURA, VANTAS, SUPPRELIN LA and DELATESTRYL. The Company established a reserve for DELATESTRYL which approximated \$1,515,000 as of December 31, 2008, and September 30, 2008, respectively.

*G. Property, Plant and Equipment*

Property, plant and equipment consisted of the following:

	Useful Lives	December 31, 2008	September 30, 2008
Manufacturing and office equipment	2 -7 years	\$ 6,435,000	\$ 6,366,000
Leasehold improvements	5 -10 years	6,830,000	6,830,000
Construction in progress		320,000	124,000
		13,585,000	13,320,000
Less: accumulated depreciation and amortization		(4,761,000)	(4,096,000)
Property, plant and equipment, net		\$ 8,824,000	\$ 9,224,000

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Depreciation and amortization expense for property, plant and equipment was approximately \$666,000 and \$486,000 for the three months ended December 31, 2008 and 2007, respectively.

### *H. Basic and Diluted Loss per Common Share*

During the three month period ended December 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 10,041,000 shares of Common Stock at prices ranging from \$2.69 to \$8.72 with various expiration dates up to November 4, 2018. Additionally, during the three month period ended December 31, 2008, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect, were as follows: (i) \$71,925,000 of 6.25% Convertible Senior Notes due in July 2009 (the Convertible Notes 2009 ) which are convertible into a total of 10,806,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2009; (ii) options to purchase 3,367,000 shares of Common Stock at

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prices ranging from \$1.22 to \$2.45 with various expiration dates up to December 2, 2018; (iii) unvested restricted stock with service-based vesting criteria of 540,230 shares and unvested restricted stock awards with service and market-based vesting criteria of 640,816 to 1,083,653 contingently issuable shares; and (iv) unvested deferred stock units with service vesting criteria of 86,667 shares of Common Stock.

During the three month period ended December 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 359,000 shares of Common Stock at prices ranging from \$7.50 to \$8.72 with expiration dates ranging up to November 6, 2017. Additionally, during the three month period ended December 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) \$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 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 12,765,000 shares of Common Stock at prices ranging from \$1.22 to \$7.41 with expiration dates ranging up to December 4, 2017; (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 350,400 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 40,000 shares of Common Stock.

Certain of the above securities contain anti-dilution provisions which may result in a change in the exercise price or number of shares issuable upon exercise or conversion of such securities.

*I. Agreements*

*Pagoclone*

*Teva*

In September 2008, the Company entered into a development, license and commercialization agreement with Teva Pharmaceutical Industries Ltd. (Teva) for the exclusive, worldwide rights to pagoclone (the Teva Agreement). The Teva Agreement became effective in November 2008. Under the terms of the Teva Agreement, the Company will conduct, and Teva will reimburse expenses for, a Phase IIB study for stuttering.

Following the completion of a successful Phase IIB study, the Teva Agreement provides for the parties to share equally development and marketing costs and future profits for the U.S., and the Company would receive certain potential milestone payments. Under certain circumstances, either party may convert the Teva Agreement from the equal sharing arrangement to a royalty structure where Teva will be responsible for all development and commercial costs in the U.S., and the Company would receive royalties on potential net sales, in addition to milestones. In either case, if the arrangement continues, Teva will be responsible for the conduct of all remaining development and commercialization, including the Phase III program.

Under the Teva Agreement, the Company could receive up to \$92,500,000 in U.S. and European development milestones and payments, including an estimated \$11,000,000 of contractual payments to be received during the Phase IIB study. In the event of a conversion to the royalty structure, in addition to the \$92,500,000 of milestones and payments, the Company could receive up to \$50,000,000 in U.S.-based sales threshold milestones. For territories outside of the U.S., Teva will be responsible for all future development and commercialization, and the Company will receive milestones and royalties on net sales.

The term will extend on a country-by-country basis from the effective date to the later of 12 years from first commercial sale or the last valid claim in a country in the territory. Teva may terminate the Teva Agreement (i) by giving notice within a certain time frame from the completion of the Phase IIB study, and (ii) anytime with a specified advance notice, except no such termination will be effective until the completion of any ongoing Phase IIB clinical trial. If Teva terminates the Teva Agreement after a product is approved, the Company will pay Teva royalties on its revenues up to an aggregate of certain amounts expended by Teva on development and commercialization. Either party may terminate the Teva Agreement upon certain customary conditions of breach.

During the three months ended December 31, 2008, the Company received \$3,000,000 related to the Teva Agreement. The Company is recognizing revenue as a component of contract and license fee revenue under the proportional performance method. Total revenue recognized during the three months ended December 31, 2008 was approximately \$255,000. The remaining \$2,745,000 has been reflected as short-term deferred revenue as of December 31, 2008.





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### *IP 751*

#### *Cervelo Pharmaceuticals*

In October 2007, the Company licensed its worldwide rights to IP 751 to Cervelo Pharmaceuticals, Inc. Cervelo was responsible for the development and marketing of IP 751. Cervelo issued its notice of termination to Indevus, which became effective in December 2008.

#### *Burstein Agreement*

The Company licensed IP751 from Sumner Burstein, PhD. The Company issued its notice of termination of the Burstein license which became effective in December 2008.

#### *SANCTURA and SANCTURA XR*

In January 2009, Allergan and the Company agreed to extend its co-promotion agreement from March 31, 2009 to September 30, 2009 for approximately \$2,300,000 to be received over this period. The extension permits details performed in the second position.

### *J. Notes*

#### *Non-recourse Notes*

On August 26, 2008, the Company closed a private placement to institutional investors of \$105,000,000 in aggregate principal amount of 16% non-convertible, non-recourse, secured promissory notes due 2024 ( *Non-recourse Notes* ).

In connection with the transaction, a \$10,000,000 interest reserve was established to fund potential interest shortfalls, or if none, for repayment of principal due under the notes. Approximately \$5,346,000 and \$3,199,000 of this reserve is classified as current and non-current restricted cash, respectively, on the Company's consolidated balance sheet as of December 31, 2008. These funds were taken from the debt proceeds. Approximately \$1,455,000 of restricted cash was used to fund the \$3,220,000 debt service payment made in November 2008. All debt service under these Non-recourse Notes is funded by Allergan's royalty payments and the balance of the restricted cash for any short falls. Applicable royalties received for any quarter that exceed the interest payments and expenses due for that quarter, will be applied to the repayment of principal of the Non-recourse Notes until the Notes have been paid in full. Any portion of the principal amount of the Non-recourse Notes not repaid on or before the legal final maturity date of November 5, 2024, will be payable on that date. In addition, the Non-recourse Notes may be redeemed at the Company's option on any quarterly payment date, subject to the payment of a redemption premium if repaid on or before November 5, 2012. After November 5, 2012, the Non-recourse Notes may be redeemed without premium.

#### *K. 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.



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At December 31, 2008, the Company has an accrued liability of approximately \$400,000 for Redux-related expenses, including legal expenses. The amount the Company ultimately pays could differ significantly from the amount currently accrued at December 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 December 31, 2008, the Company had an outstanding insurance claim of approximately \$3,000,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to the Company by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. In fiscal 2008, the Company received a partial payment of \$400,000 from Reliance pertaining to this claim and an additional \$300,000 was received in the three months ended December 31, 2008. 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 \$525,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$525,000 reflected as a noncurrent insurance claim receivable at December 31, 2008. It is uncertain when, if ever, the Company will collect any of its remaining \$3,000,000 of 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.

*L. Accrued Expenses*

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

	December 31, 2008	September 30, 2008
Compensation related	\$ 8,260,000	\$ 6,975,000
Shire royalty buy-out	2,306,000	1,078,000
Clinical and sponsored research	2,290,000	1,788,000
Professional fees	1,202,000	1,107,000
Sales and marketing	966,000	699,000
Manufacturing and production costs	833,000	731,000
Other	3,736,000	3,738,000
	\$ 19,593,000	\$ 16,116,000

*M. Fair Value Measurements*

The Company adopted SFAS No. 157 as of October 1, 2008, to measure the fair value of certain of its financial assets required to be measured on a recurring basis. Under SFAS No. 157, based on the observability of the inputs used in the valuation techniques, the Company is required to provide the following information according to the fair value hierarchy. The fair value hierarchy ranks the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2008, the Company's cash and cash equivalents of \$125,555,000 and restricted cash of \$8,545,000 are all valued using quoted prices generated by market transactions involving identical assets, or Level 1 assets as defined under SFAS No. 157.

### *N. Restructuring*

On June 30, 2008, the Company announced a restructuring of its operations to more appropriately align its cost structure to revenue projections and development opportunities. The accrued restructuring balance was approximately \$371,000 as of December 31, 2008, consisting primarily of unpaid separation costs, which are expected to be paid by June 30, 2009.

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The following table summarizes the charges and spending during the three months ended December 31, 2008 relating to the restructuring plan:

	<b>Separation Costs</b>
Balance at October 1, 2008	\$ 713,000
Payments	(261,000)
Estimate revisions	(81,000)
Balance at December 31, 2008	\$ 371,000

The Company records restructuring activities in accordance with SFAS 144, *Accounting for the Impairment and Disposal of Long-Lived Assets* and SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

*O. Recent Accounting Pronouncements*

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements*, 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. In February 2008, the FASB released Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides for delayed application of SFAS No. 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those years. The Company adopted certain provisions of SFAS No. 157 effective October 1, 2008 (see Note M, *Fair Value Measurements*, to the consolidated financial statements for additional information). The Company is currently evaluating the effect that the adoption of the provisions deferred by Staff Position No. FAS 157-2 will have on its financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 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 No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company adopted the provisions of SFAS No. 159 on October 1, 2008 and did not elect to measure any new assets or liabilities at their respective fair values and therefore, the adoption of SFAS No. 159 did not have an impact on its results of operations and financial position.

On June 27, 2007, the FASB reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). Currently, under FASB Statement No. 2, *Accounting for Research and Development Costs*, nonrefundable advance payments for future research and development activities for materials, equipment, facilities, and purchased intangible assets that have no alternative future use are expensed as incurred. EITF 07-03 addresses whether such non-refundable advance payments for goods or services that have no alternative future use and that will be used or rendered for research and development activities should be expensed when the advance payments are made or when the research and development activities have been performed. The consensus reached by the FASB requires companies involved in research and development activities to capitalize such non-refundable advance payments for goods and services pursuant to an executory contractual arrangement because the right to receive those services in the future represents a probable future economic benefit. Those advance payments will be capitalized until the goods have been delivered or the related services have been performed. Entities will be required to evaluate whether they expect the goods or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment will be charged to expense. The consensus on EITF 07-03 is effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. Entities are required to recognize the effects of applying the guidance in EITF 07-03 prospectively for new contracts entered into after the effective date. The Company has evaluated the implications of this standard, which did not have a significant impact on its consolidated financial statements.

On December 12, 2007, EITF 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of the Company's collaborations existing after January 1, 2009. The Company is evaluating the

impact, if any, this Standard will have on its financial statements.

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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 the Company has not yet evaluated this statement for the impact that SFAS 141R will have on its consolidated financial statements, it 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 evaluated the implications of this standard, which does not have a significant impact on its consolidated financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures About Derivative Instruments and Hedging Activities* ( SFAS 161 ). SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. This Standard is effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect the Company's financial condition, results of operations or cash flows.

In April 2008, the FASB Staff Position ( FSP ) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP SFAS 142-3 ). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles ( GAAP ). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is evaluating the impact, if any, this Standard will have on its financial statements.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer's non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis. The Company does not expect the adoption of FSP APB 14-1 to have a material effect on its results of operations and financial condition.

## **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<sup>®</sup> (trospium chloride tablets), SANCTURA XR (once-daily SANCTURA), NEBIDO<sup>®</sup> (injectable testosterone undecanoate), VANTAS<sup>®</sup> (histrelin implant for prostate cancer) and SUPPRELIN<sup>®</sup> 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 do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, our Form 10-K for the fiscal year ended September 30, 2008. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VALSTAR, VANTAS and SUPPRELIN LA; need for additional funds and corporate partners, including for the development of our products; risks related to increased leverage; effectiveness of our sales force;



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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, SANCTURA XR and SUPPRELIN LA; the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR as well as those relating to the outstanding indebtedness of our subsidiaries; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement

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policies and/or rates for SANCTURA, SANCTURA XR, VANTAS, SUPPRELIN LA, DELATESTRYL® 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, VALSTAR, VANTAS and SUPPRELIN LA; product liability and insurance uncertainties; risks relating to the Redux-related litigation; history of operating losses and expectation of future losses; the ability of Indevus and Endo Pharmaceuticals Holdings Inc. to complete the proposed merger as well as restrictions on business activities prior to any completion of such merger; uncertainties relating to controls over financial reporting; valuation of our Common Stock; risks related to repayment of debts; 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. Also see Item 1A, Risk Factors of Part II of this Quarterly Report on Form 10-Q.

Unless the context indicates otherwise, Indevus, the Company, we, our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock to the common stock, \$.001 par value per share, of Indevus. In the United States, SANCTURA is a registered trademark of Esprit Pharma, Inc., which became a wholly-owned subsidiary of Allergan, Inc. as of October 16, 2007 (subject to our co-exclusive right to use the mark). The mark SANCTURA XR is the subject of a pending application for registration by Allergan, Inc. Outside the United States, SANCTURA is a registered trademark of the Company. The marks DELATESTRYL, VANTAS, and SUPPRELIN are also registered trademarks of ours. We also have a pending application for the registration of the mark VALSTAR. NEBIDO is a registered trademark of Bayer Schering Pharma AG, Germany. Other trademarks, trade names and service marks used in this Form 10-Q are the property of their respective owners. Symbols for trademarks and registrations are omitted hereinafter for convenience.

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, 2008. 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® and SANCTURA XR for overactive bladder ( OAB ), which we co-promote with our partner Allergan, Inc. ( Allergan ), VANTAS for advanced prostate cancer, SUPPRELIN® LA for central precocious puberty ( CPP ), and DELATESTRYL 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 for hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and the octreotide implant for acromegaly and carcinoid syndrome.

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, which we licensed to Teva Pharmaceutical Industries Ltd. ( Teva ), ALKS 27 for chronic obstructive pulmonary disease ( COPD ), which we have been jointly developing with Alkermes, Inc. ( Alkermes ), and aminocandin for systemic fungal infections, the know-how for which we licensed to Novexel S.A. ( Novexel ).

### **Tender Offer**

On January 5, 2009, we entered into a definitive Merger Agreement ( Merger Agreement ) under which Endo Pharmaceuticals Holdings Inc. ( Endo ), a Delaware corporation, and BTB Purchaser Inc. ( Purchaser ), a Delaware corporation and direct wholly-owned subsidiary of Endo, commenced a tender offer (the Offer ) to acquire 100 percent of our outstanding shares for approximately \$370,000,000, or \$4.50 per share (less any required withholding taxes and without interest), in cash and contractual rights to receive up to an additional \$267,000,000, or \$3.00 per share, in cash payable by Endo in the future upon achievement of certain milestones related to NEBIDO and the octreotide implant ( Contingent Cash Payments ). The transaction has been approved by the boards of directors of Indevus and Endo.

The first Contingent Cash Payment relates to NEBIDO and is payable as follows: (i) \$2.00 per share if NEBIDO is approved by the FDA, within three (3) years of the closing of the tender offer, by the FDA for marketing and sale without certain restrictive labeling, or (ii) up to two potential payments in the event that NEBIDO is approved by the FDA with certain restrictive labeling, comprised of: (a) \$1.00 per share upon such approval, if FDA approval is obtained within three (3) years of the closing of the tender offer and (b) an additional \$1.00 per share following the achievement of a certain sales threshold milestone during the first five (5) years from the date of the first commercial sale of NEBIDO.



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The second Contingent Cash Payment relates to the octreotide implant and consists of \$1.00 per share to be paid in the event that, within four (4) years of the closing of the tender offer, octreotide is approved by the FDA for marketing and sale for the treatment of acromegaly or carcinoid syndrome.

Pending at least a majority of the outstanding shares of our common stock on a fully diluted basis being tendered in the Offer and the satisfaction of other customary closing conditions, and subject to certain extension rights, the tender offer is scheduled to close in the second fiscal quarter of 2009.

### **Product Developments**

#### Pagoclone

On September 25, 2008, we entered into a Development, License and Commercialization Agreement with Teva (the Teva Agreement ) for the exclusive, worldwide rights to pagoclone. Under the terms of the Teva Agreement, which became effective in November 2008, we will conduct and Teva will reimburse us for our expenses for a Phase IIb study. Following the completion of a successful Phase IIb study, the Teva Agreement provides for us to participate on a 50/50 basis with Teva in the U.S., sharing development, commercialization and marketing costs, and splitting future profits, in addition to receiving milestone payments. Under certain circumstances, either party may convert the Teva Agreement from the 50/50 arrangement to a royalty structure where Teva will be responsible for all development and commercial costs in the U.S., and we would receive royalties on net sales, in addition to milestones. In either case, if the arrangement continues, Teva will be responsible for the conduct of the Phase III program. For territories outside of the U.S., Teva will be responsible for all future development and commercialization and we will receive milestones and royalties on net sales.

Under the Teva Agreement, we could receive up to \$92,500,000 (including the Phase IIb study contractual payments) for U.S. and European development milestones and Research and Development reimbursement. In the event of a conversion to the royalty structure, in addition to the \$92,500,000 of milestones and reimbursements, we could receive up to \$50,000,000 in U.S. based sales threshold milestones.

During the three months ended December 31, 2008, we received \$3,000,000 of the estimated \$11,000,000 of contractual payments pursuant to the Phase IIb trial. We are recognizing revenue as a component of contract and license fee revenue under the proportional performance method. Total revenue recognized during the three months ended December 31, 2008 was approximately \$255,000.

#### SANCTURA XR

In January 2009, Allergan and us agreed to extend our co-promotion agreement from March 31, 2009 to September 30, 2009 for approximately \$2,300,000 to be received over this period. The extension permits details performed in the second position.

#### VALSTAR

In August 2007, we received an approvable letter from the FDA asking for clarification regarding manufacturing validation protocols and for additional data on the manufacturing process. We submitted a response to the approvable letter in October 2007. In December 2007, we received a non-approvable letter from the FDA for VALSTAR related to its chemistry, manufacturing and controls ( CMC ) NDA supplement submitted to the FDA in May 2007. The letter was received following our response to an August 2007 approvable letter.

We believe the VALSTAR-specific issues that caused the 2002 withdrawal of the product from the market have been satisfactorily resolved. However, based on the December 2007 non-approvable letter, deficiencies were identified with respect to our third-party manufacturing facility for VALSTAR that require resolution prior to approval. We believe that successfully addressing the deficiencies at the manufacturing plant is the only remaining item for product approval. In addition, we have made a decision to pursue an alternative manufacturer in parallel.

We anticipate resolving these manufacturing issues qualifying an alternative manufacturer during the first half of calendar 2009. If marketing clearance is received, we intend to commercialize VALSTAR in the U.S. utilizing our specialty sales force. Additionally, we are evaluating opportunities for the use of VALSTAR in other indications and potential clinical development requirements of such opportunities.

### **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

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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 primarily of goodwill, VANTAS, our patented HYDRON® Polymer Technology (the HYDRON Polymer Technology), and the Shire asset. SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, requires that an intangible asset subject to amortization be reviewed for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. We did not record any impairment charges related to intangible assets during the three months ended December 31, 2008. 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 incur any triggering events within the three months ended December 31, 2008 that would warrant an interim goodwill impairment assessment, and consequently, we did not record any impairment charges during the three months ended December 31, 2008.

We amortize the carrying value of the VANTAS and the HYDRON Polymer Technology assets using the straight-line method over useful lives of 14 years for VANTAS, 17 years for the HYDRON Polymer Technology and approximately 6.5 years for the Shire asset. Annual amortization expense is expected to be approximately \$2,500,000 for each of the next 5 years. For the three months ended December 31, 2008 and 2007, we recognized \$637,000 and \$497,000, respectively, of amortization expense.

### *Revenue Recognition Policy*

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. 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), 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, and since October 2007, sales of SANCTURA and SANCTURA XR product. 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

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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.

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

We executed the Allergan Agreement effective on October 16, 2007. 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 all payments received on the effective date, over the approximately 5-year performance period. All subsequent 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. There were no changes to our assessment for the three months ended December 31, 2008.

*Insurance Claim Receivable*

As of December 31, 2008, we had an outstanding insurance claim of approximately \$3,000,000, 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 ). In fiscal 2008, we received a partial payment of \$400,000 from Reliance pertaining to this claim, and during the three months ended December 31, 2008, we received an additional payment of \$300,000. 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 \$525,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately \$2,500,000 against the insurance claim on Reliance as of December 31, 2008 is a significant estimate reflecting management's judgment. It is uncertain when, if ever, we will collect any of our remaining \$3,000,000 of claims. If we incur 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, we will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments. To the extent we do not collect the insurance claim receivable of \$525,000 we would





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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 December 31, 2008 and September 30, 2008, 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.

### *Debt Issuance Costs*

We incurred financing costs associated with the issuance of debt securities. We amortize those costs over the contractual or estimated expected life of the related debt issuance to result in a constant rate of interest when applied to the amount outstanding at the beginning or ending period or other methods where the results would not be materially different as set forth in Accounting Principles Board ( APB ) 21, *Interest on Receivables and Payables* , paragraph 15.

### *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 December 31, 2008 and 2007, we used a weighted-average expected stock-price volatility of 86.5% and 46%, respectively. There were no stock option grants issued to executives during the three months ended December 31, 2008. For stock option grants issued to executives during the three months ended December 31, 2007, we used a weighted-average expected stock-price volatility of 50%. 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 to non-executives during the three months ended December 31, 2008 and 2007, we used a weighted-average expected option life assumption of 6.0 and 6.25 years, respectively. For stock option grants made to executives during the three months ended December 31, 2007, we used a weighted-average expected option life assumption of 8.0 years.

During the three months ended December 31, 2008, the Board of Directors approved modifications to extend the term of certain outstanding fully vested options, and we recorded \$448,000 of noncash compensation expense related to these modifications. Pursuant to FAS123R, we are required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of stock options.

We have also granted restricted stock units and performance stock awards. The value of these awards is being expensed over the respective vesting period. For the three months ended December 31, 2008 and 2007, we recognized \$299,000 and \$305,000, respectively, in stock-based compensation related to these restricted stock units and performance stock awards.

Inclusive of the above stock-based compensation, during the three months ended December 31, 2008 and 2007, we recognized \$1,775,000 and \$1,610,000, respectively, in total stock-based compensation.

### *Use of Estimates*

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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.

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

Our net loss for the three month period ended December 31, 2008 was \$(7,586,000), or \$(0.10) per share, basic and diluted, a decrease of \$7,117,000 from the \$(14,703,000), or \$(0.19) per share, basic and diluted, reported for the three month period ended December 31, 2007. The decreased net loss in the three months ended December 31, 2008 is primarily the result of increased sales of VANTAS and SUPPRELIN LA and an increase in contract and license fee revenue related to the SANCTURA franchise. In addition, we incurred less research and development and marketing expenses. These decreases were partially offset by increased interest expense during the three months ended December 31, 2008, related to our Non-recourse Notes issued in August 2008.

Total revenues for the three month period ended December 31, 2008 were \$26,397,000, an increase of \$9,999,000, or 61%, from the \$16,398,000 reported for the three month period ended December 31, 2007.

Product revenue for the three month period ended December 31, 2008 was \$13,061,000, an increase of \$5,763,000, or 79%, from the \$7,298,000 reported for the three month period ended December 31, 2007. The increase in product revenue is primarily the result of an increase in net sales of SUPPRELIN LA and VANTAS of approximately \$3,700,000 and \$2,900,000, respectively. We believe the increase in sales related to SUPPRELIN LA is being driven by market acceptance, as the product has now been commercially available for approximately one year. We also believe the increase in VANTAS sales is primarily driven by increased market penetration and commencement of sales to our European partner, Orion Corporation. We believe that reserves for returns and allowances are not material to our net sales.

Contract and license fee revenues for the three month period ended December 31, 2008 were \$13,336,000, an increase of \$4,236,000, or 47%, from the \$9,100,000 reported for the three month period ended December 31, 2007. In the three months ended December 31, 2008, we recognized \$12,723,000 of contract and license fee revenue related to the Allergan Agreement using the CAPM, which is an increase of \$4,148,000, compared to \$8,575,000 recognized during the three months ended December 31, 2007. Revenues increased due to the cumulative catch up and current year application of the CAPM for new receipts received in fiscal 2009. As of December 31, 2008, we have approximately \$173,214,000 of deferred revenue related to the Allergan Agreement which is expected to be recognized under the CAPM through September 30, 2012.

Cost of revenue for the three month period ended December 31, 2008 was \$6,534,000, an increase of \$679,000, or 12%, from the \$5,855,000 reported for the three month period ended December 31, 2007. Costs associated with sales of VANTAS and SUPPRELIN LA increased \$1,079,000 for the three month period ended December 31, 2008, and are consistent with the increase in our product sales of VANTAS and SUPPRELIN LA. These increases were partially offset by decreased sales of DELATESTRYL.

Research and development expense for the three month period ended December 31, 2008 was \$5,188,000, a decrease of \$1,203,000, or 19%, from the \$6,391,000 reported for the three month period ended December 31, 2007. The decrease is primarily due to decreased external product development costs for NEBIDO of approximately \$800,000, approximately \$422,000 related to pagoclone and approximately \$368,000 for the biodegradable stent. Offsetting these decreases was an increase of approximately \$863,000 for Phase III clinical costs associated with the octreotide implant. As a result of the Teva Agreement, we commenced in November 2008 a Phase IIb clinical trial program estimated to cost approximately \$12,000,000 that will extend through fiscal 2010, of which an estimated \$11,000,000 will be reimbursed by Teva. We have incurred approximately \$277,000 of related expenses during the three months ended December 31, 2008.

Marketing, general and administrative expense for the three month period ended December 31, 2008 was \$15,948,000, a decrease of \$1,818,000, or 10%, from the \$17,766,000 reported for the three month period ended December 31, 2007. Marketing expense for the three month period ended December 31, 2008 was \$10,396,000, a decrease of \$621,000, or 6%, from the \$11,017,000 reported for the three month period ended December 31, 2007. Included in the decrease is a reduction of approximately \$1,500,000 in pre-marketing costs related to NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR. Offsetting the reduction was an increase of approximately \$1,200,000 in sales force commissions primarily as a result of increased product sales of SUPPRELIN LA and VANTAS.

General and administrative expense for the three month period ended December 31, 2008 was \$5,552,000, a decrease of \$1,197,000, or 18%, from the \$6,749,000 reported for the three month period ended December 31, 2007. Included in the decrease of general and administrative expense for the three month period ended December 31, 2008 is a reduction in compensation of approximately \$535,000 due to cost savings associated with our restructuring activities. Consulting and outside service fees declined approximately \$592,000 from the same period in 2007, related to temporary assistance and outside consulting services. In addition, we incurred a one-time lease abandonment charge of approximately \$430,000 during the same period last year related to our Valera facility and increased legal fees primarily in connection with the Merger Agreement.

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We amortize our VANTAS and the HYDRON Polymer Technology intangible assets, acquired from Valera, over fourteen to seventeen years and the Shire asset acquired in fiscal 2008 over approximately 6.5 years. We recorded amortization expense of \$637,000 and \$497,000 related to these intangible assets during the three months ended December 31, 2008 and 2007, respectively.

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Investment income for the three month period ended December 31, 2008 was \$596,000, a decrease of \$524,000, or 47%, from the \$1,120,000 reported for the three month period ended December 31, 2007. The decrease in investment income in the three month period ended December 31, 2008 is the result of lower average interest rates.

Interest expense for the three month period ended December 31, 2008 was \$6,272,000, an increase of \$4,560,000, or 266%, from the \$1,712,000 reported for the three month period ended December 31, 2007. Interest expense, including amortization of original debt issuance costs and accretion of the discounted carrying value of the Convertible Notes 2009, of approximately \$1,753,000 and \$1,712,000 related to our Convertible Notes 2009 for the three months ended December 31, 2008 and 2007, respectively. In addition, during the three months ended December 31, 2008, we recorded approximately \$4,400,000 of interest expense, including amortization of offering costs, related to our Non-recourse Notes issued in August 2008. Total interest expense, including amortization of offering costs, related to our Non-recourse Notes is expected to be approximately \$16,514,000 during fiscal 2009. Total interest expense, including amortization of original debt issuance costs and accretion of the discounted carrying value of the Convertible Notes 2009, related to our Convertible Notes 2009 is expected to be approximately \$5,550,000 during fiscal 2009.

We expect to continue to incur a net loss in fiscal 2009.

## **Liquidity and Capital Resources**

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

At December 31, 2008, we had consolidated cash and cash equivalents of \$125,555,000 compared to consolidated cash and cash equivalents of \$131,306,000 at September 30, 2008. This decrease of \$5,751,000 is primarily the result of net cash used in operating activities of \$(7,040,000), offset by the release of restricted cash reserved in connection with the issuance of our Non-recourse Notes in August 2008 of approximately \$1,455,000 (see Analysis of Cash Flows ).

We are continuing to invest substantial amounts in the ongoing sales activities related to our marketed products SANCTURA and SANCTURA XR, SUPPRELIN LA and VANTAS. If approved by the FDA, we expect to invest in launch and marketing activities related to VALSTAR. We are also continuing to invest substantial amounts in our product candidates including NEBIDO, the octreotide implant and pagoclone. We believe our current and expected cash resources are sufficient to fund our operations into approximately the first calendar quarter of 2010. We 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 operating 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 Notes 2009 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.

In August 2008, Royalty Sub, our wholly-owned subsidiary, closed the private placement to institutional investors of \$105,000,000 in aggregate principal amount of the Non-recourse Notes. Royalty Sub is obligated to make quarterly debt service payments, which commenced November, 2008. These payments are funded by the quarterly royalty payments received by Royalty Sub from Allergan. Applicable royalties received for any quarter that exceed the interest payments and expenses due for that quarter, will be applied to the repayment of principal of the Non-recourse Notes until the Notes have been paid in full. Any portion of the principal amount of the Non-recourse Notes not repaid on or before the legal final maturity date of November 5, 2024, will be payable on that date. In addition, the Non-recourse Notes may be redeemed at our option on any quarterly payment date, subject to the payment of a redemption premium if repaid on or before November 5, 2012. After November 5, 2012, the Non-recourse Notes may be redeemed without premium.

In connection with the transaction, a \$10,000,000 interest reserve was established to fund potential interest shortfalls, or if none, for repayment of principal due under the Non-recourse Notes. Approximately \$5,346,000 and \$3,199,000 of this reserve is classified as current and non-current restricted cash, respectively, on our consolidated balance sheet as of December 31, 2008. These funds were taken from the debt proceeds. Approximately \$1,455,000 of restricted cash was released from reserves to fund the debt service payment on the Non-recourse Notes during the three months ended December 31, 2008. Deferred financing costs of approximately \$4,300,000 were paid by Royalty Sub to complete the

transaction. These came out of the debt proceeds and will be expensed over the expected term of 6.2 years.

Product Development

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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 December 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: \$26,655,000 for PRO 2000 and \$10,345,000 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 December 31, 2008 through the preparation of an NDA for our core development compounds as follows: approximately \$9,000,000 for PRO 2000 and \$8,000,000 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. We are currently considering strategic partners for future development and commercialization of PRO 2000.

**Analysis of Cash Flows****Net cash used in operating activities**

For the three months ended December 31, 2008, 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 three month period ended December 31, 2008 of \$(7,040,000) consisted primarily of (i) the net loss of \$7,586,000, (ii) an increase in accounts receivable of \$2,189,000 primarily related to the increase in sales volume of VANTAS and SUPPRELIN LA, and (iii) a decrease in deferred revenue of \$4,702,000 related to SANCTURA and SANCTURA XR. This was partially offset by (i) an increase in accrued liabilities of approximately \$4,450,000 primarily due to interest payable in connection with the Non-recourse Notes and increased clinical costs for the octreotide implant study, and (ii) \$3,880,000 of noncash charges for stock-based compensation, depreciation and amortization and note discount amortization.

Net cash provided by operating activities in the three month period ended December 31, 2007 of \$9,748,000 consisted primarily of (i) a \$29,961,000 increase in deferred revenue from payments from Allergan, net of amortization, and (ii) \$3,618,000 of noncash stock-based compensation, lease abandonment charges and depreciation and amortization, partially offset by (i) the net loss of \$14,703,000, (ii) an increase in accounts receivable of \$3,177,000 primarily due to increased sales of SUPPRELIN LA and amounts owed per the Allergan Agreement, and (iii) a decrease in accrued expenses and other liabilities of \$2,279,000.

Net cash used in operating activities of \$(7,040,000) for the three months ended December 31, 2008 increased \$16,788,000 from net cash provided by operating activities of \$9,748,000 for the three months ended December 31, 2007. The change in deferred revenue resulted in a reduction of cash provided by operations of \$34,663,000 as there was an increase in deferred revenue from Allergan in the three months ended December 31, 2007 due to a receipt of approximately \$33,000,000. This was partially offset by our decrease in net loss of approximately \$7,117,000 for the three month period ended December 31, 2008 compared to the three month period ended December 31, 2007. In addition, the change in our accrued expenses and other liabilities increased approximately \$6,729,000 from the three months ended December 31, 2007, primarily due to interest payable on the Non-recourse notes and the incurrence of our liability to Shire.

**Net cash used in investing activities**





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For the three months ended December 31, 2008, net cash used in investing activities of \$267,000 resulted from purchases of property, plant and equipment.

For the three months ended December 31, 2007, net cash used in investing activities of \$451,000 resulted from purchases of property, plant and equipment.

Net cash used in investing activities of \$267,000 for the three months ended December 31, 2008 decreased \$184,000 from net cash used in investing activities of \$451,000 for the three months ended December 31, 2007, due primarily to fewer acquisitions of capital equipment.

Net cash provided by financing activities

For the three months ended December 31, 2008, net cash provided by financing activities of \$1,556,000 resulted from the release of restricted cash reserved in connection with our Non-recourse Notes, as well as 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 three months ended December 31, 2007, net cash provided by financing activities of \$1,861,000 was the result of common stock issued from exercises of stock options.

Net cash provided by financing activities of \$1,556,000 for the three months ended December 31, 2008 decreased \$305,000 from \$1,861,000 for the three months ended December 31, 2007, due primarily to a decrease in exercises of stock options.

## **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. In February 2008, the FASB released Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides for delayed application of SFAS No. 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those years. We adopted certain provisions of SFAS No. 157 effective October 1, 2008. We are currently evaluating the effect that the adoption of the provisions deferred by Staff Position No. FAS 157-2 will have on our financial position and results of operations.

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 adopted the provisions of SFAS No. 159 on October 1, 2008 and did not elect to measure any new assets or liabilities at their respective fair values and therefore, the adoption of SFAS No. 159 did not have an impact on our results of operations and financial position.

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 have evaluated the implications of this standard, which did not have a significant impact on our consolidated financial statements.

On December 12, 2007, EITF 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of our collaborations existing after January 1, 2009. We are evaluating the impact, if any; this Standard will have on our financial statements.

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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

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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 evaluated the implications of this standard, which does not have a significant impact on our consolidated financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures About Derivative Instruments and Hedging Activities* ( SFAS 161 ). SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. This Standard is effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect our financial condition, results of operations or cash flows.

In April 2008, the FASB Staff Position ( FSP ) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP SFAS 142-3 ). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles ( GAAP ). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are evaluating the impact, if any, this Standard will have on our financial statements.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer's non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis. We do not expect the adoption of FSP APB 14-1 to have a material effect on our results of operations and financial condition.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We do not own derivative financial instruments in our investment portfolio.

**Interest Rate Risk related to Cash, Cash Equivalents and Marketable Securities**

We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars and are subject to interest rate risk, and could decline in value if interest rates fluctuate. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and we have implemented guidelines limiting the duration of investments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

**Risk related to the Convertible Notes 2009**

The fair value of our Convertible Notes 2009 is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes 2009 are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes 2009. 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 \$0. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes 2009. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a \$1,000 Note by approximately \$8. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes 2009 due to fluctuations in

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market value of our Common Stock or interest rates could vary substantially from these examples.

### Risk related to the Non-recourse Notes

A 10% increase or decrease in market interest rates pertaining to the Non-recourse Notes would not have a material impact on our consolidated financial statements.

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**Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of December 31, 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 December 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**

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

*Tender Offer Litigation:* In January, 2009, five lawsuits were filed in connection with the Offer. Two of these suits were filed in Massachusetts and three were filed in Delaware. The lawsuits filed in Delaware were each filed in the Court of Chancery of the State of Delaware and include Case No. 4276-CC filed on January 9, 2009 by Arthur Gober, CGM IRA Beneficiary Custodian, Beneficiary of Jerome Gober, Case No. 4299-CC filed on January 20, 2009 by H. Steven Mishket and Case No. 4327 filed on January 30, 2009 by Stefen Hell (the Hell Action). The lawsuits filed in Massachusetts were each filed in the Superior Court of the State of Massachusetts, County of Suffolk, and include Case No. 09-0126-BLS filed on January 12, 2009 by Malena S. Schroeder and Case No. 09-0166-BLS filed on January 13, 2009 by Martin Wexler.

The plaintiffs in these lawsuits are purported holders of shares of our common stock (Company's Shares), and are purportedly acting on behalf of a putative class of holders of the Company's Shares. These suits name as defendants us, the members of our Board of Directors, and in certain

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instances the Purchaser and Endo. These suits allege, among other things, that the Company and its directors breached their fiduciary duties to our stockholders by agreeing to the Offer and related merger (the Merger ) at an unfair

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and inadequate price, failing to provide our stockholders with material information to make an informed decision as to whether to tender their Company Shares in the Offer and agreeing to an excessively high termination fee. These suits seek, among other relief, (i) class action status, (ii) an order preliminarily and permanently enjoining the defendants from proceeding with the Offer, (iii) if the transaction is consummated prior to entry of a final judgment, a judgment rescinding the Offer and/or Merger or awarding rescissory damages, (iv) an order directing the defendants to account for all damages caused by them and all profits and special benefits obtained as a result of their breaches of fiduciary duties, and (v) an award to plaintiffs of the costs of the action, including reasonable attorneys' and experts' fees and expenses.

With respect to all of the cases described above, while the Company believes that each of such lawsuits is entirely without merit and that it has valid defenses to all claims, in an effort to minimize the cost and expense of any litigation relating to such lawsuits, on February 4, 2009, the Company entered into a memorandum of understanding (MOU) with the parties to such purported class action lawsuits, except for the Hell Action, pursuant to which the Company and the other defendants agreed to settle the stockholder lawsuits, except for the Hell Action. Subject to court approval and further definitive documentation, the MOU resolves the allegations by the plaintiffs in such cases against the Company and other defendants in connection with the Offer and the Merger and provides a release and settlement by the purported class of the Company's stockholders of all claims against the Company and other defendants and their affiliates and agents in connection with the Offer and the Merger. In the event that the MOU is not approved and such conditions are not satisfied, the Company will continue to vigorously defend these actions.

In addition, due to the timing of the filing of the Hell Action and other factors, the Hell Action was not included as part of the MOU and the Company and its directors intend to vigorously defend such suit.

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

### **Item 1A. Risk Factors**

*There have been no material changes to the risk factors as set forth in the Company's Annual Report filed on Form 10-K for the year ended September 30, 2008 except as follows:*

***If our planned acquisition by Endo Pharmaceuticals is not consummated, our business, results of operations and the market price of our common stock could be adversely affected.***

On January 5, 2009, we announced that we had entered into a Merger Agreement with Endo Pharmaceuticals Holdings Inc. (Endo), a Delaware corporation, pursuant to which Endo and BTB Purchaser Inc. (Purchaser), a Delaware corporation and direct wholly-owned subsidiary of Endo, have commenced a tender offer (the Offer) at an offer price of \$4.50 per share in cash (less any required withholding taxes and without interest), plus contractual rights to receive up to an additional \$3.00 per share in contingent cash consideration payments, to acquire all of the outstanding shares of our common stock (the Shares). Under the terms of the Merger Agreement, if at least a majority of the outstanding Shares on a fully diluted basis are tendered and the other conditions to the Offer are satisfied, Purchaser must promptly purchase all of the tendered Shares. Following completion of the Offer, BTB will merge with and into Indevus (the Merger) and we will become a wholly-owned subsidiary of Endo, thus ending our existence as a standalone publicly-traded company. The announcement and pending completion of the terms of the Merger Agreement, the Offer and the Merger could have an adverse effect on our business generally, our customer relationships and operating results, and our ability to retain employees, including key employees.

In addition, in the event that the conditions to the completion of the Offer and the Merger are not satisfied, or an event, change, or other circumstance occurs that could give rise to the termination of the Merger Agreement, the Offer and the Merger may not be completed. Failure to complete the Merger with Endo could negatively impact our stock price and future business and operations. For example,



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if the Merger Agreement is terminated, we may be required in specific circumstances, to pay a termination fee of up to \$18 million to Endo,

the price of our common stock may decline to the extent that the current market price reflects an assumption that the Offer and the Merger will be completed, and

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we must pay our expenses related to the Offer and the Merger, including substantial legal and accounting fees, even if the Merger is not completed. This could affect our results of operations for the period during which the fees are incurred.

Further, if the Offer or the Merger is not completed, we may experience negative reactions from the financial markets and our customers, suppliers and employees. For example, during the pendency of the transaction we will incur substantial integration costs, our employees and management will likely be distracted, it may be difficult for us to pursue and obtain our previously announced strategic initiatives and goals. Current and prospective employees may experience uncertainty about their future role with us and Endo until Endo's strategies are announced or executed. This may adversely affect our ability to attract and retain key management, research and development, sales and marketing and other personnel.

Each of the factors described above could materially and adversely affect our business, results of operations and the market price and trading volume of our common stock. In particular, if the Offer and the Merger are not completed for any reason, the market price of our common stock will likely decline, to the extent that the current market price reflects the market assumption that the Offer and the Merger will be completed or the market's perceptions as to the reasons why the Offer and the Merger were not completed.

***Restrictions on the conduct of our business prior to the completion of the Offer and the Merger may negatively impact our results of operations and our competitive position.***

We are subject to certain restrictions under the Merger Agreement on the conduct of our business prior to the completion of the Merger, including, among others, not exceeding a certain amount in capital expenditures, not making acquisitions other than those contemplated by the Merger Agreement, not entering into contracts exceeding a certain amount and other matters. These restrictions may prevent us from pursuing attractive business opportunities that may arise prior to the completion of the Merger that could be favorable to our operations and our shareholders. As a result, if the Offer and the proposed Merger are not completed, our results of operations and competitive position may be adversely affected.

**Item 6. Exhibits**

(a) Exhibits

- 3.1 Restated Certificate of Incorporation of Registrant, as amended (1)
- 3.2 By-Laws of Registrant, as amended and restated December 4, 2007 (2)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (3)
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (3)
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer (3)
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Michael W. Rogers, Chief Financial Officer (3)

- (1) Incorporated by reference to 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 10, 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) Filed with this report.

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INDEVUS PHARMACEUTICALS, INC.

Date: February 4, 2009

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 4, 2009

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 4, 2009

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