

INDEVUS PHARMACEUTICALS INC

Form 10-Q

February 08, 2008

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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, 2007**

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

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

**Outstanding at**  
**February 7, 2008**  
**76,794,326 shares**

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|  | December 31,<br>2007 | September 30,<br>2007 |
|--|----------------------|-----------------------|
| <b>ASSETS</b>  |                      |                       |
| Current assets:  |                      |                       |
| Cash and cash equivalents  | \$ 82,300            | \$ 71,142             |
| Accounts receivable, net   | 10,426               | 7,249                 |
| Inventories, net   | 9,193                | 7,729                 |
| Prepaid and other current assets   | 5,453                | 4,708                 |
| <b>Total current assets</b>  | <b>107,372</b>       | <b>90,828</b>         |
| Property, plant and equipment, net   | 9,736                | 9,771                 |
| Insurance claim receivable   | 1,258                | 1,258                 |
| Prepaid debt issuance costs  | 173                  | 253                   |
| Inventories, net   | 661                  | 682                   |
| Goodwill   | 48,244               | 48,244                |
| Intangible assets, net   | 28,693               | 29,190                |
| Other assets   | 2,509                | 2,824                 |
| <b>Total assets</b>  | <b>\$ 198,646</b>    | <b>\$ 183,050</b>     |
| <b>LIABILITIES</b>   |                      |                       |
| Current liabilities:   |                      |                       |
| Accounts payable   | \$ 2,706             | \$ 4,505              |
| Accrued expenses   | 21,397               | 24,704                |
| Accrued interest   | 2,075                | 950                   |
| Deferred revenue   | 41,137               | 21,946                |
| Convertible notes  | 75                   | 75                    |
| <b>Total current liabilities</b>   | <b>67,390</b>        | <b>52,180</b>         |
| Convertible notes  | 68,540               | 68,037                |
| Deferred revenue   | 147,285              | 136,515               |
| Other  | 1,004                | 656                   |
| <b>STOCKHOLDERS DEFICIT</b>  |                      |                       |
| Convertible Preferred Stock, \$.001 par value, 5,000,000 shares authorized:  |                      |                       |
| Series B, 239,425 shares issued and outstanding (liquidation preference at December 31, 2007 of \$3,023)   | 3,000                | 3,000                 |
| Series C, 5,000 shares issued and outstanding (liquidation preference at December 31, 2007 of \$504)   | 500                  | 500                   |
| Common Stock, \$.001 par value, 200,000,000 shares authorized; 76,675,170 and 76,360,039 shares issued and outstanding at December 31, 2007 and September 30, 2007, respectively | 77                   | 76                    |
| Additional paid-in capital   | 502,054              | 498,587               |
| Accumulated deficit  | (591,204)            | (576,501)             |
| <b>Total stockholders deficit</b>  | <b>(85,573)</b>      | <b>(74,338)</b>       |

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|   |            |            |
|---|------------|------------|
| Total liabilities and stockholders' deficit | \$ 198,646 | \$ 183,050 |
|---|------------|------------|

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

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**INDEVUS PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For the three months ended December 31, 2007 and 2006**  
**(Unaudited)**  
**(Amounts in thousands except per share data)**

|  | <b>Three months ended<br/>December 31,</b> |                    |
|--|--|--------------------|
|  | <b>2007</b>                                | <b>2006</b>        |
| <b>Revenues:</b>   |  |                    |
| Product revenue  | \$ 7,298                                   | \$ 5,257           |
| Contract and license fees  | 9,100                                      | 7,894              |
| <b>Total revenues</b>  | <b>16,398</b>                              | <b>13,151</b>      |
| <b>Costs and expenses:</b>   |  |                    |
| Cost of product revenues   | 5,855                                      | 4,276              |
| Research and development   | 6,391                                      | 9,919              |
| Marketing, general and administrative                                | 17,766                                     | 9,003              |
| Amortization of intangibles  | 497  |                    |
| <b>Total costs and expenses</b>                                      | <b>30,509</b>                              | <b>23,198</b>      |
| <b>Loss from operations</b>  | <b>(14,111)</b>                            | <b>(10,047)</b>    |
| Investment income  | 1,120                                      | 1,040              |
| Interest expense   | (1,712)                                    | (1,292)            |
| <b>Net loss</b>  | <b>\$ (14,703)</b>                         | <b>\$ (10,299)</b> |
| <b>Net loss per common share, basic and diluted</b>                  | <b>\$ (0.19)</b>                           | <b>\$ (0.18)</b>   |
| <b>Weighted average common shares outstanding, basic and diluted</b> | <b>76,307</b>                              | <b>55,847</b>      |

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

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**INDEVUS PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the three months ended December 31, 2007 and 2006**  
**(Unaudited)**  
**(Amounts in thousands)**

|  | <b>For the three months ended<br/>December 31,</b> |                  |
|--|--|------------------|
|  | <b>2007</b>  | <b>2006</b>      |
| <b>Cash flows from operating activities:</b>   |  |                  |
| Net loss   | \$ (14,703)  | \$ (10,299)      |
| <b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b> |  |                  |
| Depreciation and amortization  | 983  | 66               |
| Note discount amortization   | 583  | 165              |
| Noncash stock-based compensation   | 1,610  | 1,274            |
| Lease abandonment  | 442  |                  |
| Inventory impairment   |  | 1,100            |
| <b>Changes in assets and liabilities:</b>  |  |                  |
| Accounts receivable  | (3,177)  | (2,566)          |
| Inventories  | (1,443)  | 424              |
| Prepaid and other assets   | (430)  | 238              |
| Accounts payable   | (1,799)  | (533)            |
| Accrued expenses and other liabilities   | (2,279)  | 2,607            |
| Deferred revenue   | 29,961   | 5,853            |
| <b>Net cash provided by (used in) operating activities</b>                                       | <b>9,748</b>                                       | <b>(1,671)</b>   |
| <b>Cash flows from investing activities:</b>   |  |                  |
| Purchases of property and equipment  | (451)  | (90)             |
| Proceeds from maturities and sales of marketable securities                                      |  | 5,956            |
| Prepaid acquisition costs  |  | (1,240)          |
| <b>Net cash provided by (used in) investing activities</b>                                       | <b>(451)</b>                                       | <b>4,626</b>     |
| <b>Cash flows from financing activities:</b>   |  |                  |
| Net proceeds from issuance of common stock   | 1,861  | 243              |
| <b>Net cash provided by financing activities</b>   | <b>1,861</b>                                       | <b>243</b>       |
| <b>Net change in cash and cash equivalents</b>   | <b>11,158</b>                                      | <b>3,198</b>     |
| Cash and cash equivalents at beginning of period   | 71,142   | 70,169           |
| <b>Cash and cash equivalents at end of period</b>  | <b>\$ 82,300</b>                                   | <b>\$ 73,367</b> |

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, 2007.

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

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

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

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

*B. Accounting Policies*

*Revenue Recognition:* Product revenue consists primarily of revenues from sales of products and royalties. Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company's licensed technologies and are generally reported to the Company in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time 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.

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer, provided that the price is fixed and determinable. Product sales are reflected net of any reserves for chargebacks, returns and allowances.

Contract and license fee revenue consists of revenue from contractual and milestone payments received from partners, including amortization of deferred revenue from contractual payments.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the



arrangement as the Company completes its performance obligation,

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unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized.

The Company's business strategy includes entering into collaborative license, development or co-promotion agreements with strategic partners for the development and commercialization of the Company's products or product candidates. The terms of the agreements typically include non-refundable license fees, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. In multiple element arrangements where the Company has continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. The Company records such revenue as contract and license fee revenue.

Revenues from milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. The Company records such revenue as contract and license fee revenue.

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

*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 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 not considered available to fund current operations. The Company classifies its investments in debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time the investments are purchased. 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, 2007 and September 30, 2007, the Company had no marketable securities.

*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 the adoption of 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, 2007 and 2006, the Company used a weighted-average expected stock-price volatility of 46% and 59%, respectively. For stock option grants to executives during the three months ended December 31, 2007 and 2006, the Company used a weighted average expected stock-price volatility of 50% and 63%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. The Company also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended December 31, 2007 and 2006, the Company used a weighted-average expected option life assumption of 6.25 for non-executives and 8.0 years for executives. A shorter expected term would result in a lower compensation expense.

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

**Table of Contents***C. Valera Acquisition*

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

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

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

The following represents the unaudited pro forma results of the ongoing operations for Indevus and Valera as though the acquisition of Valera had occurred at the beginning of the three month period ended December 31, 2006. The unaudited pro forma information, however, is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results.

|   | <b>Three months ended<br/>December 31, 2006<br/>(Pro forma)</b> |
|---|---|
| Revenue                                       | \$ 16,355,000   |
| Net loss                                      | \$ (66,681,000)   |
| Net loss per common share (basic and diluted) | \$ (0.88)   |

*D. Inventories*

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ( FIFO ) method. The components of inventory are as follows:

|                 | <b>December 31, 2007</b> | <b>September 30, 2007</b> |
|-----------------|--------------------------|---------------------------|
| Raw materials   | \$ 2,160,000             | \$ 771,000                |
| Work in process | 4,516,000                | 4,405,000                 |
| Finished goods  | 3,178,000                | 3,235,000                 |
|                 | \$ 9,854,000             | \$ 8,411,000              |

All of the Company's inventories at the balance sheet date relate to commercially approved products: SANCTURA XR, VANTAS, SUPPRELIN LA and DELATESTRYL. The Company has classified \$661,000 and \$682,000 of DELATESTRYL inventory as noncurrent as of December 31, 2007 and September 30, 2007, respectively.



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Property, plant and equipment consisted of the following:

|   | Useful Lives | December 31, 2007 | September 30, 2007 |
|---|--------------|-------------------|--------------------|
| Manufacturing and office equipment              | 2 - 7 years  | \$ 4,805,000      | \$ 4,373,000       |
| Leasehold improvements                          | 5 - 10 years | 6,801,000         | 6,309,000          |
| Construction in process                         |              | 538,000           | 1,011,000          |
|   |              | 12,144,000        | 11,693,000         |
| Less: accumulated depreciation and amortization |              | (2,408,000)       | (1,922,000)        |
| Property, plant and equipment, net              |              | \$ 9,736,000      | \$ 9,771,000       |

Depreciation and amortization expense for property, plant and equipment for the three months ended December 31, 2007 and 2006 was approximately \$486,000 and \$66,000, respectively.

*F. Basic and Diluted Loss per Common Share*

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.

During the three month period ended December 31, 2006, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 1,237,000 shares of Common Stock at prices ranging from \$5.92 to \$20.13 with expiration dates ranging up to December 19, 2016. Additionally, during the three month period ended December 31, 2006, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) 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; (ii) options to purchase 11,014,000 shares of Common Stock at prices ranging from \$1.22 to \$6.68 with expiration dates ranging up to October 16, 2016; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iv) unvested restricted stock with service-based vesting criteria of 265,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 255,750 to 426,250 contingently issuable shares.

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

*G. Agreements**Allergan/Esprit*

In September 2007, the Company entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. ( Esprit ), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired

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Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, the Company received an up-front license fee, partially creditable by Allergan against future payments to the Company, of \$25

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million. The Allergan Agreement also grants the Company the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately \$123 million over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. In addition, the Company will receive approximately \$9 million in annual sales force subsidy for fiscal year 2008 which can be extended for up to six months at the Company's option. Third-party royalties paid by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will be reimbursed to the Company. The Company will also manufacture and supply SANCTURA XR through June 30, 2008, and SANCTURA through September 30, 2012, to Allergan at cost. The Company may also receive a long-term commercialization milestone payment of \$20 million related to generic competition.

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

*Plantex*

The Company has a supply agreement with Plantex USA Inc. whereby Plantex will supply it with the active pharmaceutical ingredient for VALSTAR called Valrubicin. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by June 30, 2008. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the United States, the Company will have certain minimum purchase requirements.

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

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

At December 31, 2007, the Company has an accrued liability of approximately \$500,000 for Redux-related expenses, including legal expenses. The amount the Company ultimately pays could differ significantly from the amount currently accrued at December 31, 2007. 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, 2007, the Company had an outstanding insurance claim of approximately \$3,700,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to the Company by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available

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facts and circumstances. The amount the Company collects could differ from the \$1,258,000 reflected as a noncurrent insurance claim receivable at December 31, 2007. It is uncertain when, if ever, the Company will collect any of its \$3,700,000 of estimated claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the \$5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

*I. Other*

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

|                                    | December 31, 2007 | September 30, 2007 |
|------------------------------------|-------------------|--------------------|
| Compensation related               | \$ 5,912,000      | \$ 5,351,000       |
| Clinical and sponsored research    | 4,866,000         | 9,048,000          |
| Manufacturing and production costs | 3,053,000         | 2,243,000          |
| Sales and marketing                | 2,331,000         | 2,903,000          |
| Milestone payment                  | 1,500,000         | 1,500,000          |
| Professional fees                  | 1,139,000         | 895,000            |
| Other                              | 2,596,000         | 2,764,000          |
|                                    | \$ 21,397,000     | \$ 24,704,000      |

*J. Income Taxes*

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

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

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

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as a component of tax expense. This policy did not change as a result of the adoption of FIN 48. For the quarter ended December 31, 2007, the Company did not recognize any accrued interest and penalties in its consolidated statement of operations or its consolidated balance sheet.

*K. Liquidity*

The Company is subject to risks common to companies in the biotechnology 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



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to fund its current and planned operations. The Company expects to continue to incur substantial expenditures for the development, commercialization and

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marketing of its products and will need to raise additional funds 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.

*L. Recent Accounting Pronouncements*

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements* ( SFAS 157 ), which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. The Company is evaluating the implications of this standard, but does not currently expect it to have a significant impact.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is evaluating the implications of this standard, but does not currently expect it to have a significant impact.

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

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

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

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

Statements in this Form 10-Q that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any



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products, including SANCTURA<sup>®</sup> (trospium chloride tablets), SANCTURA XR (once-daily SANCTURA), NEBID<sup>®</sup> (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 and do not refer to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company's Form 10-K for the fiscal year ended September 30, 2007. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL<sup>®</sup> and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, and VALSTAR; product liability and insurance uncertainties; risks relating to the Redux-related litigation; need for additional funds and corporate partners, including for the development of our products; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; difficulties in managing our growth; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this Form 10-Q. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements.

The following discussion should be read in conjunction with our unaudited consolidated financial statements and notes thereto appearing elsewhere in this report and audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2007. Unless the context indicates otherwise, Indevus, the Company, we, our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock refers to the Common Stock, \$.001 par value per share, of Indevus.

**Our Business**

We are a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Our approved products include SANCTURA<sup>®</sup> and SANCTURA XR for overactive bladder ( OAB ), which we co-promote with our partner Allergan, Inc. ( Allergan ), VANTAS<sup>®</sup> for advanced prostate cancer, SUPPRELIN<sup>®</sup> LA for central precocious puberty ( CPP ), and DELATESTRYL<sup>®</sup> for the treatment of hypogonadism. We market our products through an approximately 100-person specialty sales force.

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

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

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

**Recent Product Developments**

SANCTURA XR

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In September 2007, we entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. ( Esprit ), which re-defined the obligations of each party and superseded all previous agreements

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pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement ). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, we received an up-front license fee, partially creditable by Allergan against future payments to us, of \$25 million. The Allergan Agreement also grants us the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately \$123 million over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. In addition, we will receive approximately \$9 million in annual sales force subsidy for fiscal year 2008 which can be extended for up to six months at our option. Third-party royalties paid by us as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will be reimbursed to us. We will also manufacture and supply SANCTURA XR through June 30, 2008, and SANCTURA through September 30, 2012, to Allergan at cost. We may also receive a long-term commercialization milestone payment of \$20 million related to generic competition.

**NEBIDO**

In January 2008, we announced the final results of an additional Phase III pharmacokinetic trial for NEBIDO. The data from the trial showed that NEBIDO met its primary endpoints, including a responder analysis based on an average testosterone concentration during the steady state dosing interval and an outlier analysis based on the maximum testosterone concentration during the steady state dosing interval. In addition, the drug was well-tolerated.

**VALSTAR**

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

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

**IP 751**

In October 2007, we licensed our worldwide rights to IP 751 to Cervelo and received an upfront payment of \$1,000,000. This revenue was deferred as of December 31, 2007. The revenue will be recognized after all contractual obligations have been fulfilled. In addition, we could receive further payments based on regulatory and, if approved for marketing, commercial achievements and royalties based upon net sales. Cervelo is responsible for all future development, manufacturing, marketing and financial obligations relating to IP 751.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements that have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reported periods. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates.

*Goodwill and Other Intangible Assets*

Our intangible assets consist of goodwill, VANTAS and our patented Hydron Technology. The Hydron Technology is a proprietary, non-biodegradable, reservoir-based drug delivery process involving a device designed to be inserted under a patient's skin allowing the release of drugs continuously, at even, controlled rates for periods up to twelve months (the



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Hydron Technology ). SFAS 142, *Goodwill and Other Intangible Assets*, requires that periodic tests of goodwill for impairment be performed and that the other intangibles be amortized over their useful lives unless those lives are determined to be indefinite. SFAS 142 requires that goodwill be tested for impairment under a two-step impairment process at least annually or more frequently whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. We did not record any impairment charges during the three month period ended December 31, 2007.

We amortize the carrying value of the VANTAS and the Hydron Technology assets using the straight-line method over useful lives of 14 years for VANTAS and 17 years for the Hydron Technology. Annual amortization expense is expected to be approximately \$2 million. For the three months ended December 31, 2007, we recognized \$497,000 of amortization expense.

### *Revenue Recognition Policy*

Product revenue consists primarily of revenues from sales of products and royalties. Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and are generally reported to us in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based. If the royalty report for such period is received subsequent to the time 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.

We record sales of product as product revenue upon the later of shipment or as title passes to our customer, provided that the price is fixed and determinable. Product sales are reflected net of any reserves for chargebacks, returns and allowances.

Contract and license fee revenue consists of revenue from contractual and milestone payments received from partners, including amortization of deferred revenue from contractual payments.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized.

Our business strategy includes entering into collaborative license, development or co-promotion agreements with strategic partners for the development and commercialization of our products or product candidates. The terms of the agreements typically include non-refundable license fees, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. In multiple element arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as we complete our performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. We record such revenue as contract and license fee revenue.

Revenues from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. We record such revenue as contract and license fee revenue.

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





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

We executed the Allergan Agreement effective on October 16, 2007. The terms and conditions of the Allergan Agreement required an assessment of the expected term of the agreement and our obligations thereunder. 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 ). We determined we had multiple deliverables for which the fair value of each deliverable was not determinable and concluded that the Allergan Agreement 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 will recognize the deferred revenue balances that existed on the effective date, and the incremental license payment of \$25 million, over the approximately 5-year obligation period. All future payments received from Esprit during the approximately 5-year obligation period, including royalties, sales force reimbursement and product revenue, will be amortized using the Contingency-Adjusted Performance Model ( CAPM ). All payments received after the approximately 5-year obligation period will be recognized as revenue when earned, provided that there are no remaining obligations.

Until the October 16, 2007 effective date of the Allergan Agreement, we were recording the initial and milestone payments received from PLIVA and Esprit as deferred revenue and amortizing each component into revenue using the CAPM over the estimated twelve year duration of our prior collaboration with Esprit commencing on the date such payments were received.

After consideration of the estimated performance periods as noted above, we amortized \$8,575,000 and \$5,646,000 of deferred revenue into contract and license fee revenue during the three months ended December 31, 2007 and 2006, respectively, and the balance of deferred revenue related to the Allergan Agreement at December 31, 2007 was \$186,349,000.

### *Redux-Related Liabilities*

At December 31, 2007, we have an accrued liability of approximately \$500,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at December 31, 2007. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

### *Insurance Claim Receivable*

As of December 31, 2007, we had an outstanding insurance claim of approximately \$3,700,000, for services rendered through May 30, 2001 by the group of law firms defending us in the Redux-related product liability litigation. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company ( Reliance ), which is in liquidation proceedings. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately \$2,400,000 against the insurance claim on Reliance as of September 30, 2007 is a significant estimate reflecting management's judgment. To the extent we do not collect the insurance claim receivable of \$1,258,000 we would be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

### *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 not considered available to fund current operations. We classify our investments in debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time the investments are purchased. 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, 2007 and September 30, 2007, we had no marketable securities.

### *Inventory Capitalization Policy*

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ( FIFO ) method. We expense costs related to inventory until such time as FDA approval is obtained for a new product, at which time we commence capitalization of costs relating to that product.



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**Table of Contents***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 were required to make significant estimates related to the adoption of SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended December 31, 2007 and 2006, we used a weighted-average expected stock-price volatility of 46% and 59%, respectively. For stock option grants to executives during the three months ended December 31, 2007 and 2006, we used a weighted average expected stock-price volatility of 50% and 63%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended December 31, 2007 and 2006, we used a weighted-average expected option life assumption of 6.25 for non-executives and 8.0 years for executives. A shorter expected term would result in a lower compensation expense.

*Use of Estimates*

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

**Results of Operations**

Our net loss increased \$4,404,000 to \$(14,703,000), or \$(0.19) per share, basic, in the three month period ended December 31, 2007 from \$(10,299,000), or \$(0.18) per share, basic, in the three month period ended December 31, 2006. The increased net loss in the three month period ended December 31, 2007 is primarily the result of increased sales and marketing expense related to products acquired through our acquisition of Valera, partially offset by increased revenues from sales of VANTAS and SUPPRELIN LA and decreased research and development costs.

Total revenues increased \$3,247,000, or 25%, to \$16,398,000 in the three month period ended December 31, 2007 from \$13,151,000 in the three month period ended December 31, 2006.

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

Product revenue increased \$2,041,000 or 39%, to \$7,298,000 in the three month period ended December 31, 2007 from \$5,257,000 in the three month period ended December 31, 2006. Included in revenue for the three month period ended December 31, 2007 is \$3,576,000 and \$2,262,000 of revenue resulting from the sales of VANTAS and SUPPRELIN LA, respectively, both of which were obtained through our acquisition of Valera in April 2007. Included in revenue for the three month period ended December 31, 2006 is \$1,883,000 of revenue related to product and royalty revenue resulting from our prior collaboration with Esprit.

Contract and license fee revenues increased \$1,206,000 or 15%, to \$9,100,000 in the three month period ended December 31, 2007 from \$7,894,000 in the three month period ended December 31, 2006. The increase in contract and license fee revenue is due primarily to the receipt of a \$25 million milestone payment from Allergan in October 2007 which, along with the previously deferred revenue, is now being recognized over a five year CAPM which replaces the previous twelve year CAPM through October 16, 2007. In addition, product and royalty payments resulting from the Allergan collaboration are accounted for under the CAPM as of the October 16, 2007 effective date of the amended collaboration. Such revenues had previously been reflected as product and royalty revenues when the product was shipped and when the royalties were due and payable from Esprit. As of December 31, 2007, we have \$186,349,000 of deferred revenue related to the Allergan Agreement which is expected to be recognized under CAPM through September 30, 2012.



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Cost of product revenue increased \$1,579,000, or 37%, to \$5,855,000 in the three month period ended December 31, 2007 from \$4,276,000 in the three month period ended December 31, 2006. Included in this increase is an increase in costs of \$2,572,000 related to sales of VANTAS.

Research and development expense decreased \$3,528,000 or 36%, to \$6,391,000 in the three month period ended December 31, 2007 from \$9,919,000 in the three month period ended December 31, 2006. External product development costs related to trospium decreased approximately \$4,700,000 in the three month period ended December 31, 2007 because the product was approved in August 2007. External product development costs for PRO 2000 decreased approximately \$500,000. Partially offsetting these decreased external development costs during the three months ended December 31, 2007 were increased external product development costs of \$1,000,000 incurred for products obtained through our purchase of Valera, including \$900,000 for VALSTAR and the octreotide and naltrexone implants.

Marketing, general and administrative expense increased \$8,763,000, or 97%, to \$17,766,000 in the three month period ended December 31, 2007 from \$9,003,000 in the three month period ended December 31, 2006.

Marketing expense increased \$6,198,000, or 129%, to \$11,017,000 in the three month period ended December 31, 2007 from \$4,819,000 in the three month period ended December 31, 2006. This increase is primarily the result of advertising and other marketing expense for VANTAS and SUPPRELIN LA and pre-launch costs related to NEBIDO and VALSTAR.

General and administrative expense increased \$2,565,000, or 61%, to \$6,749,000 in the three month period ended December 31, 2007 from \$4,184,000 in the three month period ended December 31, 2006. Included in the general and administrative expense for the three month period ended December 31, 2007 is increased compensation expense of approximately \$950,000 related primarily to higher staffing levels and increased outside services expense of approximately \$600,000 related primarily to our acquisition of Valera and increased business development activities. Also included in general and administrative expense for the three month period ended December 31, 2007 is a charge of \$442,000 related to a sublease of a portion of our Cranbury facilities.

In connection with our acquisition of Valera, we acquired certain intangible assets, including VANTAS and the Hydron Technology. We have recorded amortization expense of \$497,000 during the three month period ended December 31, 2007 related to these intangible assets. The annual amortization of these intangible assets is expected to be approximately \$2,000,000. The estimated life of these intangible assets is fourteen to seventeen years.

Interest expense relates to our \$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 ). Interest expense of approximately \$1,712,000 in the three months ended December 31, 2007 includes \$1,125,000 of interest to be paid, approximately \$83,000 of amortization of original debt issuance costs, and approximately \$503,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 and their face value. Total interest expense in fiscal 2008 is expected to be approximately \$6,650,000, and will include \$2,150,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value.

**Liquidity and Capital Resources**

**Cash, Cash Equivalents and Marketable Securities**

At December 31, 2007 we had consolidated cash and cash equivalents of \$82,300,000 compared to consolidated cash and cash equivalents of \$71,142,000 at September 30, 2007. This increase of \$11,158,000 is primarily the result of net cash provided by operating activities of \$9,748,000 (see Analysis of Cash Flows ).

We are continuing to invest substantial amounts in the ongoing development of our product candidates and sales activities related to our marketed products SANCTURA, SUPPRELIN LA and SANCTURA XR. In fiscal 2008, we expect to invest in pre-marketing activities related to NEBIDO and, if the product is approved, launch and marketing activities. If approved by the FDA, we also expect to invest in launch and marketing activities related to VALSTAR. We are continuing to invest in the development of NEBIDO. We may purchase inventory of NEBIDO prior to FDA approval in order to be ready to launch NEBIDO soon after approval. We believe we have sufficient cash for currently planned expenditures for at least the next twelve months.

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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.

On August 6, 2007, we completed our offer to exchange the \$72,000,000 of outstanding 6.25% Convertible Senior Notes due July 2008 (the Old Notes ), for an equal amount of our 6.25% Convertible Senior Notes due July 2009 (the New Notes ) (the Exchange Offer ). Holders of \$71,925,000 of the Old Notes accepted the Exchange Offer. Consequently, we have \$71,925,000 of the New Notes as a component of long term liabilities and \$75,000 of the Old Notes outstanding and classified as a component of current liabilities as of December 31, 2007. If the New Notes do not convert into common stock by July 15, 2009, we will be required to redeem these New Notes for cash.

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

### Product Development

There can be no assurance that results of any ongoing or future pre-clinical or clinical trials will be successful, that additional trials will not be required, that any drug or product under development will receive FDA approval in a timely manner or at all, or that such drug or product could be successfully manufactured in accordance with U.S. current Good Manufacturing Practices, or successfully marketed in a timely manner, or at all, or that we will have sufficient funds to develop or commercialize any of our products.

Total research and development expenses incurred by us through December 31, 2007 on our core development compounds, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: \$23,000,000 for PRO 2000, \$2,200,000 for the octreotide implant, and \$1,300,000 for the biodegradable ureteral stent. 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, 2007 through the preparation of an NDA for our core development compounds as follows: approximately \$14,000,000 for PRO 2000, \$9,000,000 for the octreotide implant and \$2,000,000 for the biodegradable ureteral stent. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. When we acquired Valera on April 18, 2007, the following products were in development and unapproved: SUPPRELIN LA, the octreotide implant and the biodegradable ureteral stent. SUPPRELIN LA was approved in May 2007 and the other products are continuing under development. We are currently considering strategic partners for future development and commercialization of PRO 2000 and evaluating commercialization options for pacoclone in parallel with our ongoing development program and preliminary market development activities.

### Analysis of Cash Flows

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

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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 investing activities of \$451,000 resulted from purchases of property, plant and equipment.

Net cash provided by financing activities of \$1,861,000 is the result of common stock issued from exercises of stock options. We cannot predict if or when stock options will be exercised in the future.

### **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. We are evaluating the implications of this standard, but do not currently expect it to have a significant impact.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS 159 ). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are evaluating the implications of this standard, but do not currently expect it to have a significant impact.

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

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

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

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

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





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

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

### Risk related to the Convertible Notes

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a \$1,000 Note by approximately \$52.50. An increase in market interest rates could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, an interest rate increase of 1% could reduce the value of a \$1,000 Note by approximately \$7.50. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes due to fluctuations in the market value of our Common Stock or interest rates could vary substantially from these examples.

## **Item 4. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of December 31, 2007, 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, 2007 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

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

Subject to the qualifications set forth below, no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2007 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

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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-

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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.

*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**

*A restated description of the risk factors associated with our business is set forth below. This description includes any material changes to and supersedes the descriptions of the risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for our fiscal year ended September 30, 2007. The following factors should be reviewed carefully, in conjunction with the other information contained in this Report and our consolidated financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-Q and presented elsewhere by our management from time to time. See Part I Note Regarding Forward Looking Statements.*

#### **Risks Relating to Our Business**

***We will be dependent on our marketed products and the ability of Allergan to perform its obligations with respect to SANCTURA and SANCTURA XR.***

We expect to derive a substantial portion of our revenue in fiscal 2008 from only four products. Two of our products SANCTURA and SANCTURA XR are treatments for overactive bladder, which we co-promote with our marketing partner, Allergan. The others are VANTAS, a product for the treatment of advanced prostate cancer, and SUPPRELIN LA, for the treatment of central precocious puberty. We believe that revenues derived under our agreement with Allergan and from the sale of VANTAS and SUPPRELIN LA will continue to account for a substantial portion of our revenue for the foreseeable future.

In October 2007, Allergan became our new partner with respect to SANCTURA and SANCTURA XR in connection with its acquisition of Esprit. Our agreement with Allergan is referred to herein as the Allergan Agreement. We are highly dependent on Allergan for the commercialization and marketing of SANCTURA and SANCTURA XR in the U.S. and for performance of its obligations under the Allergan Agreement. Under the terms of the Allergan Agreement, Allergan will be responsible for all U.S. marketing and sales activities relating to SANCTURA, and SANCTURA XR (we have the right co-promote SANCTURA XR through March 2009). As such, we will depend on Allergan to devote sufficient resources to effectively market SANCTURA and SANCTURA XR. The failure of Allergan to effectively market SANCTURA or SANCTURA XR or perform its obligations under the Allergan Agreement, could materially adversely affect our business, financial condition and results of operations.

We currently market VANTAS and SUPPRELIN LA ourselves through our approximately 100-person specialty sales force. Our specialty sales force may not be able to successfully market and sell such products. Moreover, because our marketing resources are limited, we may be unable to devote sufficient resources to our marketed products to maintain, or achieve increasing, market acceptance of such products in their highly competitive marketplaces. If we are unable to successfully market and sell such products, it will have a material adverse effect on our business and results of operations.



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***Our product candidates may not be successfully developed or achieve market acceptance. In particular, we are dependent on FDA approval and market acceptance of NEBIDO.***

We currently have multiple compounds or products which are in various stages of development and have not been approved by the FDA. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances or receive such clearances on a timely basis.

We expect to derive a substantial portion of our long term revenues from the market acceptance of NEBIDO if it is approved. On November 1, 2007 we announced that the FDA accepted for review our NDA for NEBIDO. The FDA Prescription Drug User Fee Act (PDUFA) target action date for NEBIDO is June 27, 2008. On January 22, 2008 we announced that we had submitted additional data to the FDA pertaining to NEBIDO. Although we do not expect there to be a delay in the PDUFA date as a result of this submission, we would be materially adversely affected if we are unable to obtain FDA approval for NEBIDO or if the FDA should require additional testing prior to FDA approval. In addition, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse effect on the commercialization of NEBIDO. Even if NEBIDO receives regulatory clearance, there can be no assurance that it will achieve or maintain market acceptance. If NEBIDO does not achieve market acceptance it will have a material adverse effect on our business and results of operations.

We are unable to predict whether any of our other product candidates, such as VALSTAR and the octreotide implant, will receive regulatory clearances or will be successfully manufactured or marketed. On December 19, 2007 we announced that we had received a non-approvable letter from the FDA for VALSTAR due to manufacturing deficiencies identified during an FDA pre-approval inspection of our third-party manufacturing facility. Due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these product candidates receive regulatory clearance, there can be no assurance that such products will achieve or maintain market acceptance which could have a material adverse effect on our business and results of operations.

The product candidates that we are attempting to develop differ from established treatment methods and will compete with a number of more established drugs and therapies manufactured and marketed by major pharmaceutical companies. If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue and could harm our business.

***We may not compete successfully in the urology and endocrinology markets, including for sales of our products as well as the acquisition of additional compounds.***

Our products compete in the urology and endocrinology markets. The competition in the urology and endocrinology markets is intense and is expected to increase. Our products compete with many current drug therapies or with new drugs which may reach the market in the future. Launches of other competitive products may occur in the near future, and we cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales.

We compete against biotechnology companies, universities, government agencies, and other research institutions. Many of the companies who market or are expected to market competitive drugs or other products are large, multinational companies who have substantially greater marketing and financial resources and experience than us. We may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, our competitors may develop products that are safer or more effective or less expensive than those we are developing or that would render our products less competitive or obsolete.

In addition, although we will have proprietary protection for NEBIDO and other products we are developing, we could face competition from generic substitutes of these products and our other marketed products, such as SANCTURA and SANCTURA XR. Because generic manufacturers are not exposed to development risks for such generic substitutes, these manufacturers can capture market share by selling generic products at lower prices, which can reduce the market share held by the original product.

Sales of competing products may cause a decrease in the selling price or units sold for our products, and could have a material adverse effect on our net product sales, gross margin and cash flows from operations. In the event our products were unable to be sold at the rate we currently anticipate, we could potentially have excess inventory, resulting in an impairment charge that could have a material adverse effect on our financial statements.



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Many companies in the pharmaceutical industry also have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing products. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights and establishing collaborative agreements for the development and commercialization of our products.

In particular, our marketed products and near term product candidates compete against the following products:

SANCTURA and SANCTURA XR compete against anticholinergics, such as Detrol and Detrol LA (tolterodine) by Pfizer, Ditropan and Ditropan XL (oxybutynin) by Johnson & Johnson, Inc., Oxytrol (oxybutynin transdermal patch) by Watson Pharmaceuticals, Vesicare (solifenacin) by Astellas Pharma US, Inc. and Glaxo Smith Kline, Enablex (darifenacin) by Novartis A.G., generic oxybutynin, and generic oxybutynin extended release;

VANTAS competes against TAP Pharmaceutical Products Lupron and Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar, a multiple injection formulation that delivers triptorelin; AstraZeneca's Zoladex, a biodegradable rod that delivers goserelin for up to three months; and BayerSchering's Viadur, a rigid metal implant that releases leuprolide over a 12-month period;

NEBIDO, if approved and launched, will compete against gels, such as AndroGel by Solvay and Testim by Auxilium, transdermal patch systems, such as AndroDerm by Watson, and multiple injectable products currently marketed in the U.S. which require more frequent injections than NEBIDO;

SUPPRELIN LA competes against TAP Pharmaceutical Products Lupron Depot-PED; and

VALSTAR, if approved and launched, is the only product approved by the FDA for therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder.

Physicians may not prescribe, and patients may not accept, our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

the adequacy and effectiveness of our sales force and that of any co-promotion partners;

the adequacy and effectiveness of our production, distribution and marketing capabilities;

the success of competing products, including generics; and

the availability and extent of reimbursement from third-party payors.

In addition, we do not conduct our own research to discover new drug compounds. Instead, we depend on the acquisition of compounds from others for development through licensing, partnerships, corporate collaborations, strategic corporate transactions or company acquisitions. Therefore, in order to grow, we must continue to acquire and develop additional compounds. The success of this strategy depends upon our ability to identify, select and acquire compounds that meet the criteria we have established. Identifying suitable compounds is a lengthy, complex and uncertain process. In addition, we compete with other companies with substantially greater financial, marketing and sales resources, for the acquisition of compounds. We may not be able to acquire the rights to additional compounds through licensing or strategic acquisitions of selected assets or businesses, on terms we find acceptable or at all.



*We rely on third parties with respect to manufacturing, distribution and commercialization of certain of our products as well as products we have out-licensed.*

We are currently dependent on Madaus GmbH ( Madaus ) to manufacture SANCTURA, Bayer Schering Pharma AG, Germany ( BayerSchering ) to manufacture NEBIDO and third parties to manufacture SANCTURA XR. We are also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR, as well as for the packaging of SANCTURA and SANCTURA XR. If Madaus or any of these third parties were unable to achieve or maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., we would need to seek alternative sources of supply, which could create disruptions in the supply of SANCTURA, SANCTURA XR or NEBIDO. In addition, we are reliant on third parties for manufacturing relating to our non-core product candidates, such as PRO 2000 and pagoclone. Reliance on third-party manufacturers for the manufacture of most of our products, entails risks to which we would not be subject if we manufactured these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with U.S. current Good Manufacturing Practices ( cGMP ) requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are

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unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or commercialize them. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with cGMP. For example, our third-party manufacturer of VALSTAR failed to pass a recent cGMP compliance inspection and as a result, we received a non-approvable letter for VALSTAR which has delayed the approval and launch of this product. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA

We expect to seek corporate partnerships for the manufacture and commercialization of our products. We may not be successful in finding corporate partners and the terms of any such arrangements may not be favorable to us. If we are unable to obtain any such corporate partners, development of our product candidates could be delayed or curtailed, which could materially adversely affect our operations and financial condition. For example, we are currently seeking a partner for the development and commercialization of pegoclone.

Any collaborative partners may not be successful in commercializing our products or may terminate their collaborative agreements with us. If we enter into any collaborative arrangements, we will depend on the efforts of these collaborative partners and we will have limited or no control over the development, manufacture and commercialization of the products subject to the collaboration. If certain of our collaborative partners terminate the related agreements or fail to develop, manufacture or commercialize our products, we would be materially adversely affected. Because we expect generally to retain a royalty interest in sales of products licensed to third parties, our revenues may be less than if we marketed products directly.

We have out-licensed to third parties the development and commercialization efforts of many of our non-core products and product candidates such as aminocandin and IP 751. We are dependent on such third parties with respect to development and commercialization of such products and product candidates and we have limited or no influence over their efforts and activities. Reliance on third parties for such efforts entails risks, many of which we would not be subject to if we developed these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the licensing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us. In addition, the occurrence of any such events or any other failure by these third parties to adequately develop or commercialize these products or product candidates could materially adversely effect our operations and financial condition.

***As a manufacturer of some of our products, we are subject to risks of reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.***

As a manufacturer of some of our products and product candidates, we are subject to a variety of risks, including risks pertaining to reliance on single suppliers, interruptions on the manufacturing process and regulatory requirements.

We currently rely on single suppliers for some of our products and product candidates, including in particular histrelin, the active ingredient in VANTAS, SUPPRELIN LA and the octreotide implant. Any alternate sources of these raw materials and services may not be immediately available to us and may not meet specifications or requirements of us or the FDA. Consequently, if any of our suppliers are unable or unwilling to supply us with these raw materials in sufficient quantities with the correct specifications, or provide services on commercially acceptable terms, we may not be able to manufacture our products or our product candidates in a timely manner or at all, which could materially adversely effect our operations and financial condition.

Any interruption in the supply or manufacturing of our products or product candidates may adversely impact sales of our products or the development of our product candidates. Any lack of supply during such the period of such interruption may have an adverse impact on our future sales because physicians may have elected to use alternative treatments during this time frame or may, as a result of this interruption, permanently switch to another product. For example, prior to the merger with Indevus, Valera experienced two separate disruptions in its manufacturing of VANTAS due to issues caused by its supply of histrelin. These difficulties delayed the manufacturing of VANTAS for several weeks and directly impacted Valera's supply of VANTAS in 2005. Also, VALSTAR was withdrawn from the market in 2002 due to a manufacturing problem. In the future, we may experience other disruptions in our manufacturing process for these and our products and product candidates which may adversely impact sales and development.

Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used



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in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

We may also encounter problems with the following:

production yields;

raw materials;

shortages of qualified personnel;

compliance with FDA regulations, including the demonstration of purity and potency;

changes in FDA requirements;

controlling production costs; and

development of advanced manufacturing techniques and process controls.

In addition, we are required to register our manufacturing facilities with the FDA and other regulatory authorities. The facilities are subject to inspections confirming compliance with cGMP or other regulations. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, or revocation of pre-existing approval for a product, such as VANTAS or SUPPRELIN LA, which would eliminate a substantial source of our revenue and could materially adversely affect our operations and financial condition.

We also currently contract with third parties for most of our manufacturing needs and do not manufacture any of our own products or product candidates, except for VANTAS and SUPPRELIN LA. We do not currently have any substitute manufacturing facilities and arrangements in place with respect to our manufacturing facility now used for VANTAS and SUPPRELIN LA. As such, if we are unable to continue to use our current manufacturing facility for any reason, including regulatory non-compliance or otherwise, it could materially adversely affect our operations and financial condition. In addition, we cannot be certain that alternative manufacturing sources will be available on reasonable terms or at all.

To continue to develop products, apply for regulatory approvals and commercialize products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Certain of our requirements for supplies or clinical compounds are filled by purchase orders on an as-requested basis and are not the subject of long-term contracts. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of these products or product candidates on reasonable terms or at all.

***We rely on the protection provided by our intellectual property and have limited patent protection on some of our products and we are dependent on market exclusivity for some of our products.***

Our future success will depend to a significant extent on our ability to:

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obtain and enforce patent protection on our products and technologies;

maintain trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being granted or that, if granted, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged.

In addition, certain products we are developing or selling are not covered by any patents and, accordingly, we will be dependent on obtaining market exclusivity under the Waxman-Hatch Act for such products. Under the Waxman-Hatch Act, a company may obtain five years of market exclusivity if the FDA determines such compound to be a chemical entity that has not been the subject of an approved NDA in the past. The period of market exclusivity under the Waxman-Hatch Act is considerably shorter than the exclusivity period afforded by patent protection, which, in the case of some patents, may last up to twenty years from the earliest priority date of the patent directed to the product, our use or method of manufacture. If we are unable to obtain strong proprietary rights protection of our products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to our product, without being required to conduct the lengthy and expensive clinical trials required of us. Certain of our agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition.

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Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a product candidate can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing any advantage of the patent.

Our license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents used in the commercialization of the product. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product. Our ability to successfully commercialize SANCTURA in the U.S. will depend on the continued availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman-Hatch Act, which provides protections for certain new products. The Waxman-Hatch Act provides for a period of market exclusivity in the U.S. for SANCTURA for five years from the date of FDA approval, May 28, 2004. The marketing of SANCTURA could be materially adversely affected if the period of market exclusivity is shortened. After this time, there may be generic versions of tiroprium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly.

Although we have patent applications that have been published pertaining to SANCTURA XR, the applications continue to be pending and we cannot predict whether any patents will issue on such applications. If granted, there can be no assurance that these patents can or will preclude eventual market erosion from new technologies or competing products. If we are unable to obtain a patent on such formulation we will have to rely solely on market exclusivity for this formulation, which will be shorter than five years.

Further, we will not have exclusive rights with respect to the sale of VALSTAR because the product candidate is not covered by any patents or orphan drug exclusivity. As a result, competitors may compete with us by, among other things, introducing a generic version of the product or a similar product that contains the active ingredient, valrubicin.

Our business may be materially adversely affected if we fail to obtain and retain needed patents, licenses or proprietary information. Others may independently develop similar products. Furthermore, litigation may be necessary:

to enforce any of our patents;

to determine the scope and validity of the patent rights of others; or

in response to legal action against us claiming damages for infringement of patent rights or other proprietary rights or seeking to enjoin commercial activities relating to the affected product or process.

The products marketed by us or our licensees or being developed by us may infringe patents issued to competitors, universities or others. Third parties could bring legal actions against us or our sublicensees claiming patent infringement and seeking damages or to enjoin manufacturing and marketing of the affected product or the use of a process for the manufacture of such products. If any such actions are successful, in addition to any potential liability for indemnification, damages and attorneys' fees in certain cases, we could be required to obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. If a license is not available to us, we may be forced to abandon the related product. The outcome of any litigation may be uncertain. Any litigation may also result in significant use of management and financial resources.

We also rely upon unpatented proprietary technology and may determine in some cases that our interest would be better served by reliance on trade secrets or confidentiality agreements rather than patents. No assurance can be made that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to such proprietary technology or disclose such technology or that we can meaningfully protect our rights in such unpatented proprietary technology. We may also conduct research on other pharmaceutical compounds or technologies, the rights to which may be held by, or be subject to, patent rights of third parties. Accordingly, if products based on such technologies are commercialized, such commercial activities may infringe such patents or other rights, which may require us to obtain a license to such patents or other rights.

To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. Most of our consultants are employed by or have consulting agreements with third parties and any inventions discovered by such individuals will not necessarily become our property. There is a risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, which could adversely affect us.



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*The successful commercialization of our products will depend on obtaining reimbursement at adequate levels from government authorities, private health insurers and Medicare/Medicaid for patient use of these products.*

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government healthcare programs, such as Medicare and Medicaid, and private health insurers. These third party payors control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services and altering reimbursement levels. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for our current marketed products or products we may develop could affect the extent to which we are able to commercialize these products.

We cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products we may develop or, if already available, will not be decreased in the future. The U.S. Congress recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our drug products. Any reduction in demand would adversely affect our business.

In particular, Future Medicare reimbursement levels may decline for VANTAS, which would have an adverse effect on our net product sales. Reimbursement levels are currently set by the numerous Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for VANTAS based on our average selling price ( ASP ). Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to VANTAS. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. VANTAS is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, or a split policy. Finally, there are some Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which we believe make payments based upon a split policy.

We are devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, we are at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. While we are challenging the basis for these reimbursement policies with the Medicare carriers, there is no guarantee that our challenge will be successful.

Significant uncertainty generally exists as to the reimbursement status of newly approved healthcare products. Our ability to achieve acceptable levels of reimbursement for product candidates will affect our ability to successfully commercialize, and attract collaborative partners to invest in the development of, our product candidates. Reimbursement may not be available for products that we may develop and reimbursement or coverage levels may reduce the demand for, or the price of products that we may develop. If we cannot maintain coverage for our existing marketed products or obtain adequate reimbursement for other products we develop, the market for those products may be limited.

Acceptable levels of reimbursement will also have an effect on our ability to attract collaborative partners to invest in the development of, our products and product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to obtain collaborative partners to manufacture and commercialize our products and product candidates, and may not be able to obtain a satisfactory financial return on our own manufacturing and commercialization of any future products.

*To be successful, our product candidates must be accepted by the health care community, which can be very slow to adopt or be unreceptive to new products.*

Our business is dependent on market acceptance of our products by physicians, healthcare payors, patients and the medical community. Medical doctors' willingness to prescribe, and patients' willingness to accept, our products depend on many factors, including:

perceived safety and efficacy of our products;



convenience and ease of administration;

prevalence and severity of adverse side effects in both clinical trials and commercial use;

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availability of alternative treatments;

cost effectiveness;

effectiveness of our marketing strategy and the pricing of our products;

publicity concerning our products or competing products; and

our ability to obtain third-party coverage or reimbursement.

If our products are not accepted by physicians, healthcare payors, patients and the medical community, it will have a material adverse effect on our business and results of operations.

***We rely on the favorable outcome of clinical trials of our product candidates including NEBIDO and the octreotide implant.***

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical product candidates we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products we are developing may not demonstrate the safety and efficacy of such products. In particular, NEBIDO has thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drug would not change when taken in future trials or by a larger population of users.

Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-launch approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including Indevus, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. For example, while there were multiple clinical trials of pagoclone that demonstrated statistically significant efficacy, while but other trials of pagoclone were unsuccessful. These unsuccessful trials prompted Pfizer (our previous licensee of this compound) to elect not to pursue further development of the compound and to return to us all rights to pagoclone which resulted in a material adverse impact on our stock price.

***We rely on third parties to conduct certain of the clinical trials for our product candidates, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for or commercialize our product candidates.***

We design the clinical trials for our product candidates, but we rely on academic institutions, private physician offices, corporate partners, contract research organizations and other third parties to assist in the managing and monitoring of these trials. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted the trials entirely on our own. For example, we are conducting certain clinical trials for the octreotide implant in Europe; however, we have employed a contract research organization to monitor the trials. We will also contract with a third party to handle the data management for these trials.

Although we rely on, and will continue to rely on, third parties to manage the data from our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trials plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

***We have regulatory guidelines and related pricing risks.***

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Although our marketed products have been approved by the FDA, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of these products. In addition, although these products have thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drugs would not change when assessed in future trials or when used by a larger patient population.

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If our products become subject to efficacy or safety concerns, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, unexpected side effects or regulatory proceedings, the impact on our revenues could be significant.

Government health care cost-containment measures can significantly affect our sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare, pharmaceutical importation laws, and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which our products are sold.

Government agencies promulgate regulations and guidelines directly applicable to us and our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to profitably sell our marketed products and any other products that we may develop. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has been enacted by Congress and signed by the President. Additionally, Medicare regulations implementing the prescription drug benefit became effective as of January 1, 2006. These and other regulatory and legislative changes or proposals may affect our ability to raise capital, obtain additional collaborators and market our existing products and any other products that we may develop. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, our ability to sell our current marketed products and other products we may develop in commercially acceptable quantities at profitable prices may be harmed.

Third-party payors are increasingly challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that we successfully develop and are approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

***The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.***

We have worldwide rights to market many of our products and product candidates. We intend to seek approval of and market our products outside of the U.S. For example, we have agreements to license VANTAS in Canada, South Africa, Asia and Argentina. To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. Other than the approval of VANTAS for marketing in the European Union and certain other foreign jurisdictions, we may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

**Table of Contents*****We have product liability exposure and insurance uncertainties related to our products.***

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability and clinical trial insurance in the amount of \$40,000,000. We may obtain additional coverage for products that may be marketed in the future. We may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect us or other named parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. We have indemnified certain licensors, licensees and contractors and may be required to indemnify additional licensors, licensees or contractors against product liability claims incurred by them as a result of products we develop or market. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against us, our business and financial condition could be materially adversely affected. In addition, any payments made by us in connection with product liability litigation could result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

***The outcome of the Redux litigation could materially harm us.***

On September 15, 1997, we announced a market withdrawal of our first commercial prescription product, the weight loss medication Redux, which had been launched by American Home Products Corporation, now Wyeth, our licensee, in June 1996. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties 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, and 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.

On May 30, 2001, we entered into an Indemnity and Release Agreement with AHP, now Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which we are not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on our future business, results of operations or financial condition or that the potential of any such claims would not adversely affect our ability to obtain sufficient financing to fund operations. We are unable to predict whether the existence of such litigation may adversely affect our business.

Pursuant to agreements we have with Les Laboratoires Servier, from whom we in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, we may be required to indemnify such parties for Redux-related liabilities. We are unable to predict whether such indemnification obligations, if they arise, may adversely affect our business.

***We could be materially harmed if our agreements were terminated.***

Our agreements with licensors and licensees generally provide the other party with rights to terminate the agreement, in whole or in part, under certain circumstances. Many of our agreements require us to diligently pursue development of the underlying product or product candidate or risk loss of the license or incur penalties. Depending upon the importance to us of the product that is subject to any such agreement, this could materially adversely affect our business. In particular, termination of our agreements with Allergan, Madaus, or Helsinn Chemicals SA and Helsinn Advanced Synthesis SA, related to SANCTURA and SANCTURA XR, our agreements with BayerSchering, under which we license NEBIDO, or our agreement with Aventis, under which we license pagoclone, would materially harm us. The agreements with Allergan, Madaus, Aventis or BayerSchering may be terminated by any of them if we are in material breach of our agreements with them or if we become insolvent or file for bankruptcy protection. Termination of the supply agreement with Plantex USA Inc. for the supply of valrubicin, the active pharmaceutical ingredient for VALSTAR, could significantly hinder the potential to commercialize VALSTAR.

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***We will need additional funds in the near future.***

We believe that our existing cash resources will be sufficient to fund our planned operations through February 2009. Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

marketing success of SANCTURA, SANCTURA XR, VANTAS and SUPPRELIN LA;

approval, launch and marketing success of NEBIDO;

approval, launch and marketing success of VALSTAR;

the costs and progress of our research and development programs;

the timing and cost of obtaining regulatory approvals; and

the timing and cash flows of in-licensing or out-licensing products.

In addition, we continue to expend substantial funds for research and development, marketing, general and administrative expenses and manufacturing. We expect to continue to use substantial cash for operating activities in fiscal 2008 as we continue to fund our development activities for NEBIDO, the octreotide implant and other product candidates, as well as sales and marketing activities related to VANTAS, SUPPRELIN LA and VALSTAR. We are also co-promoting SANCTURA and SANCTURA XR.

We may seek or receive additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of any such transaction would be favorable to us or our security holders. If we raise additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a negative effect on our stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price.

As a result of the uncertainties and costs associated with business development activities, market conditions and other factors generally affecting our ability to raise additional funds, we may not be able to obtain sufficient additional funds to satisfy cash requirements in the future or may be required to obtain financing on terms that are not favorable to us. We may have to curtail our operations or delay development of our products.

***We have a history of losses and expect losses to continue.***

We have incurred substantial net losses over the past five fiscal years, including net losses of approximately \$31,800,000, \$68,200,000, \$53,200,000, \$50,600,000 and \$103,800,000 for fiscal years 2003, 2004, 2005, 2006 and 2007, respectively. At December 31, 2007 we had an accumulated deficit of approximately \$591,200,000.

We continue to experience losses and to use substantial amounts of cash in operating activities. We will be required to conduct significant development and clinical testing activities for the products we are developing and these activities are expected to result in continued operating losses and use of cash for the foreseeable future. We cannot predict the extent of future losses or the time required to achieve profitability.

***We may not be profitable in the future.***

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We may never achieve or sustain profitability in the future. We expect to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments. We also continue to expect fluctuations in expense from the timing of clinical trials, payments to licensors for development milestones, and in licensing fees for new product candidates.

***We may be adversely impacted if our controls over external financial reporting fail or are circumvented.***

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If we, or our independent registered public accounting firm, determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only

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reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers.

*As we continue to evolve from a company that was primarily involved in development to one also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.*

In order to continue to expand our current sales and commercialize our other product candidates, particularly NEBIDO, we currently anticipate that we will need to add managerial, selling, operational, financial and other employees over the next two years. Expansion may place a strain on our management, operational and financial resources. Moreover, higher than expected market growth of our products, the acquisition or in-licensing of additional products, as well as the development and commercialization of our other product candidates or marketing arrangements with third parties, could accelerate our hiring needs beyond our current expectations. To manage further growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our business goals.

As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls that could expose us to an increased risk of the occurrence of financial or accounting irregularities or fraud.

*We may be unable to integrate successfully the businesses of Valera and realize the anticipated benefits of the merger.*

In April 2007, we completed our merger with Valera Pharmaceuticals, Inc. The success of the merger will depend, in part, on our ability to realize the anticipated synergies, growth opportunities and cost savings from integrating Valera's business with our business. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of Valera. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among other factors:

coordinating geographically separated organizations, systems and facilities, including complexities associated with managing the combined businesses at two separate locations;

combining the sales force territories and competencies associated with the sale of products presently sold by Indevus or Valera;

integrating personnel from different companies while maintaining focus on providing consistent, high-quality products and customer service;

unforeseen expenses or delays associated with the merger; and

performance shortfalls as a result of the diversion of management's attention to the merger.

If we are unable to successfully combine the businesses of Indevus and Valera in a manner that permits the combined company to achieve the cost savings and operating synergies anticipated to result from the merger, such anticipated benefits of the merger may not be realized fully or at all or may take longer to realize than expected. In addition, it is possible that the integration process could result in the loss of key employees, the disruption or interruption of, or the loss of momentum in, inconsistencies between each company's standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or our ability to



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achieve the anticipated benefits of the merger, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company.

***We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our stock price, operating results and results of operations.***

We may acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant

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amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, the costs of manufacturing, and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular quarterly or annual periods.

### ***We depend upon key personnel and consultants.***

We have a small number of employees and are dependent on certain executive officers and scientific personnel, including Glenn L. Cooper, our Chief Executive Officer, Thomas F. Farb, our President and Chief Operating Officer, Noah D. Beerman, our Chief Business Officer, Mark S. Butler, our Chief Administrative Officer and General Counsel, Michael W. Rogers, our Chief Financial Officer, and Bobby W. Sandage, Jr., our Chief Scientific Officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees, including sales people, among pharmaceutical and biotechnology companies is intense. If key employees terminate their employment, or insufficient numbers of employees are retained to maintain effective operations, our sales, marketing or development activities and prospects might be adversely affected. In addition, we might not be able to locate suitable replacements for any key employees that leave Indevus or offer employment to potential replacements on reasonable terms.

### **Risks Relating to Our Common Stock and Other Securities**

#### ***We may issue preferred stock with rights that could affect your rights and prevent a takeover of the business.***

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock, 244,425 of which were issued and outstanding as of December 31, 2007. In addition, vesting of shares of our common stock subject to awards under our 2004 Equity Incentive Plan accelerates, and outstanding options under our stock option plans become immediately exercisable, upon certain changes in control of Indevus, except under certain conditions. In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of Indevus and, accordingly, could adversely affect the price of our common stock.

#### ***We have never paid any dividends on our common stock.***

We have not paid any cash dividends on our common stock since inception and do not expect to do so in the foreseeable future. Any dividends on our common stock will be subject to the preferential cumulative annual dividend of \$0.1253 per share and \$1.00 per share payable on our outstanding Series B preferred stock and Series C preferred stock, respectively, held by Wyeth and dividends payable on any other preferred stock we may issue.

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*If we pay cash dividends on our common stock, certain holders of our securities may be deemed to have received a taxable dividend without the receipt of any cash.*

If we pay a cash dividend on our common stock which results in an adjustment to the conversion price of our outstanding convertible notes, holders of such notes may be deemed to have received a taxable dividend subject to U.S. federal income tax without the receipt of any cash.

*The price for our securities is volatile.*

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. Future announcements concerning us or our competitors may have a significant impact on the market price of our securities. Factors which may affect the market price for our securities, among others, include:

market success of SANCTURA and VANTAS;

successful commercialization of SANCTURA XR;

successful commercialization of SUPPRELIN LA;

results of clinical studies and regulatory reviews;

marketing approval of NEBIDO;

marketing approval of VALSTAR;

sales by Valera's former stockholders of significant amounts of Indevus common stock they received in the merger or upon conversion of any contingent stock rights;

partnerships, corporate collaborations and company acquisitions;

announcements by our corporate collaboration partners concerning our products, about which we generally have very limited control, if any, over the timing or content;

changes in the levels we spend to develop, acquire or license new compounds;

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

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sales, the possibility of sales, or buybacks of Indevus common stock or other financings, including resales of stock, stock issued upon conversion of the contingent stock rights issued in connection with the merger, issuance of additional debt and entering into credit facilities;

our results of operations and financial condition including variability in quarterly operating results due to timing and recognition of revenue, receipt of licensing, milestone and royalty payments, regulatory progress and delays and timing and recognition of certain expenses;

changes in proprietary rights of our, or our competitor's, products;

Redux-related litigation developments;

public concern as to the safety or commercial value of our products; and

general economic conditions.

The high and low sales prices of our common stock as reported by the NASDAQ Global Market were: \$12.83 and \$0.85 for fiscal 2002, \$6.90 and \$1.32 for fiscal 2003, \$10.25 and \$4.86 for fiscal 2004, \$7.45 and \$2.41 for fiscal 2005, \$6.75 and \$2.50 for fiscal 2006, \$8.06 and \$5.58 for fiscal 2007 and \$8.22 and \$6.88 for the three month period ended December 31, 2007. Our common stock is subject to delisting if our stock price drops below the bid price of \$1.00 per share. If we fail to meet any of the continued listing requirements for the NASDAQ Global Market, our common stock could be delisted from the NASDAQ Global Market, the effects of which could include limited release of a market price of our common stock, limited liquidity for stockholders and limited news coverage and could result in an adverse effect on the market for our common stock.

The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our common stock.

Further, in connection with the merger we agreed under certain circumstances to register shares (less any shares sold prior to the time of registration) of our common stock acquired by SMH Capital Inc. (and affiliated entities), or SMH, in connection with the merger for resale under the Securities Act of 1933 on a Registration Statement on Form S-3. We have not yet filed any such registration statement and through December 30, 2007 any such registration statement we file would register approximately 2,300,000 shares (less any shares sold prior to the time of registration). This figure is based on filings

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made with the SEC evidencing shares received in connection with the merger and resold by SMH and its affiliates without registration pursuant to Rule 144 as promulgated under the Securities Act. When sales of Indevus common stock by SMH or any other former Valera stockholder occur, the market price of our common stock could decline. These sales may also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate to raise funds through future offerings of common stock.

***Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our merger with Valera could have an adverse impact on our results of operations and the market value of our common stock.***

The total estimated purchase price pertaining to our merger with Valera has been allocated to Valera's net tangible assets, identifiable intangible assets, in process research and development and goodwill. To the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and the market value of our common stock.

***The price for our common stock could be negatively affected if we issue additional shares or if third parties exercise registration rights.***

Wyeth has the right, under certain circumstances, to require us to register for public sale 622,222 shares of our common stock issuable to it upon conversion of the Indevus Series B and Series C preferred stock it owns. We have outstanding registration statements on Form S-3 relating to the resale of our shares of common stock and on Form S-8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. In addition, shares of our common stock may be issued upon conversion of the contingent stock rights issued in connection with the merger with Valera. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of our common stock.

***Our stockholders could be diluted if we issue our shares subject to options, warrants, convertible notes, stock awards or other arrangements.***

As of December 31, 2007, we had reserved the following shares of our common stock for issuance:

10,817,000 shares issuable in the aggregate upon conversion of the Convertible Senior Notes issued in July 2003, which are due in July 2008, referred to herein as the Old Notes (of which \$75,000 remain outstanding) and the Convertible Senior Notes issued in August 2007, which are due in July 2009, referred to herein as the New Notes (of which \$71,925,000 remain outstanding);

14,065,000 shares issuable upon exercise of outstanding options, Performance Stock Awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices;

622,222 shares upon conversion of preferred stock owned by Wyeth, subject to anti-dilution provisions; and

2,707,000 shares reserved for grant and issuance under our stock option, stock purchase and equity incentive plans.

We may grant additional options, warrants or stock awards. To the extent such shares are issued, the interest of holders of our common stock will be diluted.

In addition, we are obliged to issue shares of common stock upon achievement of development milestones related to contingent stock rights, or CSRs, issued in connection with the merger with Valera. As a result of the May 3, 2007 FDA approval of SUPPRELIN LA and our possession of a specified amount of inventory of commercially sellable units, approximately 2,300,000 shares were issued. The achievement of future milestones related to two other outstanding CSRs could result in the issuance of shares totaling approximately \$40,600,000.

***Leverage as a result of our outstanding convertible notes may harm our financial condition and results of operations.***

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At December 31, 2007, we had \$72,000,000 of outstanding debt reflected on our balance sheet relating to the Old Notes and New Notes. There currently is \$75,000 of Old Notes outstanding with a maturity date of July 15, 2008. There currently is \$71,925,000 of New Notes outstanding with a maturity date of July 15, 2009.

The noteholders may decide not to convert the New Notes. If the price of our common stock at the time the New Notes become due does not exceed \$8.50 for a specified period, then we may not be able to redeem the New Notes to cause a conversion, and then we may be obligated to repay the holders of the New Notes in cash on the July 2009 due date.

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We may incur additional indebtedness in the future and the Old Notes and New Notes do not restrict our future issuance of indebtedness. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

a portion of our cash flow from operations will be dedicated to the payment of any interest required with respect to outstanding indebtedness;

increases in our outstanding indebtedness and leverage will increase our vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and

depending on the levels of our outstanding debt, our ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

Our ability to make payments of principal and interest on our indebtedness depends upon our future performance, which will be subject to the success of our development and commercialization of new pharmaceutical products, general economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control. If we are not able to generate sufficient cash flow from operations or other sources in the future to service our debt, we may be required, among other things:

to seek additional financing in the debt or equity markets;

to refinance or restructure all or a portion of our indebtedness, including the Old Notes, New Notes or any other notes that may be issued;

to sell selected assets; or

to reduce or delay planned expenditures on clinical trials, and development and commercialization activities.

Such measures might not be sufficient to enable us to service our debt. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms.

***Our convertible senior notes may not be rated or may receive a lower rating than anticipated.***

If one or more rating agencies rates our outstanding convertible senior notes, collectively referred to herein as the Notes, assigns the Notes a rating lower than the rating expected by investors, or reduces its rating in the future, the market price of the Notes would be harmed.

***The price of the Notes may fluctuate significantly as a result of the volatility of the price for our common stock.***

Because the Notes are convertible into shares of our common stock, volatility or depressed prices for our common stock could have a similar effect on the trading price of the Notes.

***If we are unable to pay all of our debts, the noteholders will receive payment on the Notes only if we have funds remaining after we have paid any future secured indebtedness.***

The Notes are unsecured and are effectively subordinated in right of payment to any future secured indebtedness that we may incur to the extent of the value of the pledged assets. If some or all of our assets are pledged to secure other obligations, there may not be sufficient assets remaining to pay amounts due on any or all of the outstanding Notes. In addition, we may be unable to fulfill our obligations to offer to repurchase the Notes upon a change of control.

*The Notes will effectively be subordinated to the debt of our subsidiaries.*

Our right to receive any assets of any of our subsidiaries upon their liquidation or reorganization, and therefore the right of the holders of the Notes to participate in those assets, will be effectively subordinated to the claim of that subsidiary's creditors, including trade creditors. In addition, even if we were a creditor of any of our subsidiaries, our rights as a creditor would be subordinate to any security interest in the assets of our subsidiaries and any indebtedness of our subsidiaries senior to that held by us. Our subsidiaries have no obligation to pay any amounts due on the Notes or to provide us with funds for our payment obligations, whether by dividends, distributions, loans or other payments. Furthermore, we are not limited in or prohibited from transferring cash or other assets to our subsidiaries from time to time.



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**Item 6. Exhibits**

(a) Exhibits

- 3.1 Restated Certificate of Incorporation, as amended (1)
- 3.2 By-Laws of Registrant, as amended and restated December 4, 2007(2)
- 10.1 A copy of the Fiscal Year 2008 CEO Bonus Plan of Registrant (3) (\*)
- 10.2 A copy of the Fiscal Year 2008 COO and Executive VP Bonus Plan of Registrant (3) (\*)
- 10.3 Form of Amended and Restated Employment Agreement by and between the Registrant and Glenn L. Cooper, M.D. effective as of October 1, 2007(4) (\*)
- 10.4 Form of Amended and Restated Employment Agreement by and between the Registrant and Thomas F. Farb. effective as of October 1, 2007(4) (\*)
- 10.5 Form of Amended and Restated Employment Agreement by and between the Registrant and Bobby W. Sandage, Jr. effective as of October 1, 2007(4) (\*)
- 10.6 Form of Amended and Restated Employment Agreement by and between the Registrant and Michael W. Rogers effective as of October 1, 2007(4) (\*)
- 10.7 Form of Amended and Restated Employment Agreement by and between the Registrant and Mark S. Butler effective as of October 1, 2007(4) (\*)
- 10.8 Form of Amended and Restated Employment Agreement by and between the Registrant and Noah D. Beerman effective as of October 1, 2007(4) (\*)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (5)
- 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 (5)
- 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 (5)
- 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 (5)

(\*) Management contract or compensatory plan or arrangement

- (1) Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K filed with the SEC on December 14, 2005 and Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2007.
- (2) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 7, 2007.
- (3) Incorporated by reference to the Company's Form 8-K filed with the SEC on November 2, 2007.
- (4) Incorporated by reference to the Company's Form 8-K filed with the SEC on November 30, 2007.
- (5) Filed with this report.

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**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC.

Date: February 8, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 8, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 8, 2008

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