

INDEVUS PHARMACEUTICALS INC  
Form 10-Q  
May 10, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2007

or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**  
Commission File No. 0-18728

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**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)

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Registrant's telephone number, including area code: (781) 861-8444

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

|                               | Outstanding at    |
|-------------------------------|-------------------|
| Class:                        | May 8, 2007       |
| Common Stock \$.001 par value | 73,979,384 shares |

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|   | March 31,<br>2007 | September 30,<br>2006 |
|---|-------------------|-----------------------|
| <b>ASSETS</b>   |                   |                       |
| Current assets:   |                   |                       |
| Cash and cash equivalents   | \$ 59,009         | \$ 70,169             |
| Marketable securities   |                   | 5,956                 |
| Accounts receivable, net  | 4,004             | 2,851                 |
| Inventories   | 1,585             | 1,628                 |
| Prepaid and other current assets  | 4,995             | 2,598                 |
| Total current assets  | 69,593            | 83,202                |
| Property and equipment, net   | 937               | 880                   |
| Insurance claim receivable  | 1,258             | 1,258                 |
| Prepaid debt issuance costs   | 853               | 1,183                 |
| Inventories   | 1,387             | 3,293                 |
| Other assets  | 2,348             | 2,491                 |
| Total assets  | \$ 76,376         | \$ 92,307             |
| <b>LIABILITIES</b>  |                   |                       |
| Current liabilities:  |                   |                       |
| Accounts payable  | \$ 1,915          | \$ 2,917              |
| Accrued expenses  | 16,770            | 11,026                |
| Accrued interest  | 950               | 950                   |
| Deferred revenue  | 14,250            | 13,433                |
| Total current liabilities   | 33,885            | 28,326                |
| Convertible notes   | 72,000            | 72,000                |
| Deferred revenue  | 113,999           | 114,041               |
| Other   |                   | 2,144                 |
| Minority interest   | 126               | 126                   |
| <b>STOCKHOLDERS DEFICIT</b>   |                   |                       |
| Convertible Preferred Stock, \$.001 par value, 5,000,000 shares authorized:   |                   |                       |
| Series B, 239,425 shares issued and outstanding (liquidation preference at March 31, 2007 of \$3,030)   | 3,000             | 3,000                 |
| Series C, 5,000 shares issued and outstanding (liquidation preference at March 31, 2007 of \$505)   | 500               | 500                   |
| Common Stock, \$.001 par value, 120,000,000 shares authorized; 56,280,074 and 56,040,456 shares issued and outstanding at March 31, 2007 and September 30, 2006, respectively | 56                | 56                    |
| Additional paid-in capital  | 348,223           | 344,789               |
| Accumulated deficit   | (495,413)         | (472,675)             |
| Total stockholders deficit  | (143,634)         | (124,330)             |
| Total liabilities and stockholders deficit  | \$ 76,376         | \$ 92,307             |

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



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

|   | <b>Three months ended<br/>March 31,</b> |                    | <b>Six months ended<br/>March 31,</b> |                    |
|---|---|--------------------|---------------------------------------|--------------------|
|   | <b>2007</b>                             | <b>2006</b>        | <b>2007</b>                           | <b>2006</b>        |
| <b>Revenues:</b>                                    |   |                    |                                       |                    |
| Product revenue                                     | \$ 3,455                                | \$ 7,442           | \$ 8,712                              | \$ 10,871          |
| Contract and license fees                           | 7,769                                   | 6,980              | 15,663                                | 12,525             |
| <b>Total revenues</b>                               | <b>11,224</b>                           | <b>14,422</b>      | <b>24,375</b>                         | <b>23,396</b>      |
| <b>Costs and expenses:</b>                          |   |                    |                                       |                    |
| Cost of product revenue                             | 1,274                                   | 5,780              | 5,550                                 | 7,650              |
| Research and development                            | 9,272                                   | 9,434              | 19,191                                | 19,754             |
| Marketing, general and administrative               | 12,687                                  | 9,508              | 21,690                                | 17,816             |
| <b>Total costs and expenses</b>                     | <b>23,233</b>                           | <b>24,722</b>      | <b>46,431</b>                         | <b>45,220</b>      |
| Loss from operations                                | (12,009)                                | (10,300)           | (22,056)                              | (21,824)           |
| Investment income                                   | 863                                     | 802                | 1,903                                 | 1,688              |
| Interest expense                                    | (1,293)                                 | (1,293)            | (2,585)                               | (2,585)            |
| Minority interest                                   |   | (435)              |                                       | (435)              |
| <b>Net loss</b>                                     | <b>\$ (12,439)</b>                      | <b>\$ (11,226)</b> | <b>\$ (22,738)</b>                    | <b>\$ (23,156)</b> |
| <b>Net loss per common share, basic and diluted</b> | <b>\$ (0.22)</b>                        | <b>\$ (0.24)</b>   | <b>\$ (0.41)</b>                      | <b>\$ (0.49)</b>   |
| <b>Weighted average common shares outstanding:</b>  |   |                    |                                       |                    |
| Basic and diluted                                   | 55,923                                  | 47,281             | 55,885                                | 47,222             |

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 six months ended March 31, 2007 and 2006**

**(Unaudited)**

**(Amounts in thousands)**

|   | <b>For the six months ended<br/>March 31,</b> |                 |
|---|---|-----------------|
|   | <b>2007</b>                                   | <b>2006</b>     |
| Cash flows from operating activities:                                       |   |                 |
| Net loss  | \$ (22,738)                                   | \$ (23,156)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |   |                 |
| Depreciation and amortization   | 130   | 260             |
| Amortization of convertible note issuance costs                             | 330   | 330             |
| Minority interest in net income of consolidated subsidiary                  |   | 435             |
| Inventory impairment  | 1,100   |                 |
| Noncash consideration   |   | (266)           |
| Noncash stock-based compensation  | 2,645   | 2,419           |
| Changes in assets and liabilities:  |   |                 |
| Accounts receivable   | (1,153)                                       | (522)           |
| Inventories   | 848   | (5,081)         |
| Prepaid and other assets  | 859   | (816)           |
| Accounts payable  | (1,001)                                       | 565             |
| Deferred revenue  | 775   | (8,142)         |
| Accrued expenses and other liabilities                                      | 3,582   | (13)            |
| <b>Net cash used in operating activities</b>                                | <b>(14,623)</b>                               | <b>(33,987)</b> |
| Cash flows from investing activities:                                       |   |                 |
| Purchases of property and equipment   | (186)   | (138)           |
| Proceeds from maturities and sales of marketable securities                 | 5,956   | 4,122           |
| Prepaid acquisition costs   | (3,113)                                       |                 |
| <b>Net cash provided by investing activities</b>                            | <b>2,657</b>                                  | <b>3,984</b>    |
| Cash flows from financing activities:                                       |   |                 |
| Net proceeds from issuance of common stock and treasury stock               | 806   | 1,310           |
| <b>Net cash provided by financing activities</b>                            | <b>806</b>                                    | <b>1,310</b>    |
| Net change in cash and cash equivalents                                     | (11,160)                                      | (28,693)        |
| Cash and cash equivalents at beginning of period                            | 70,169  | 85,098          |
| Cash and cash equivalents at end of period                                  | \$ 59,009                                     | \$ 56,405       |

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, 2006.

Indevus Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company's approved products include SANCTURA<sup>®</sup> for overactive bladder, which it copromotes with its partner Esprit Pharma, Inc. ( Esprit ), VANTARA<sup>®</sup> for advanced prostate cancer, and DELATESTRYL<sup>®</sup> (testosterone enanthate) for the treatment of male hypogonadism, all of which are currently marketed, as well as SUPPRELIN<sup>®</sup> LA, which was recently approved for central precocious puberty. Indevus currently markets its products through an approximately 100-person specialty sales force and it has ten product candidates in development. The Indevus development pipeline contains multiple compounds within the Company's core therapeutic areas in addition to several partnered or partnerable programs. The most advanced compounds in development include SANCTURA XR<sup>®</sup>, the once-daily formulation of SANCTURA, 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 pathogens, and pagoclonone for stuttering.

On April 18, 2007, the Company acquired Valera Pharmaceuticals, Inc., a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products (see Note J). The consolidated interim financial statements included herein do not include results from Valera since the acquisition occurred after the end of the fiscal quarter ended March 31, 2007.

*B. Accounting Policies*

*Revenue Recognition:* Product revenue consists primarily of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by the Company to Madaus GmbH ( Madaus ) for SANCTURA. 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. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from partners, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities.

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, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. In multiple element arrangements where the Company has continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. The Company records such revenue as contract and license fee revenue.



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

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period the Company achieves the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission Bulletin ( SAB ) No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements.

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

*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.

*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 includes 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. At March 31, 2007 and September 30, 2006, all investments held were classified as available-for-sale. 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.

**C. Inventories**

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out ( FIFO ) method. The Company expenses costs related to inventory until such time as it receives approval from the FDA for a new product, at which time the Company commences capitalization of costs relating to that product.

The components of inventory are as follows:

|                | March 31, 2007 | September 30, 2006 |
|----------------|----------------|--------------------|
| Raw materials  | \$             | \$                 |
| Finished goods | 2,972,000      | 4,921,000          |
|                | \$ 2,972,000   | \$ 4,921,000       |

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Finished goods at March 31, 2007 and September 30, 2006 consisted of DELATESTRYL. Pursuant to the Company's acquisition of the DELATESTRYL product in 2006, the Company assumed a commitment to purchase approximately \$1.1 million of additional DELATESTRYL from a third-party supplier. As of September 30, 2006, the Company believed that the supplier had defaulted on its obligation under the purchase commitment to deliver DELATESTRYL and concluded that the Company was no longer obliged by its assumed commitment, which the supplier disputed. The Company subsequently determined that it will be cost beneficial to settle the dispute with the supplier and as a result of negotiations has estimated that it will purchase an additional quantity of DELATESTRYL at a cost of approximately \$750,000. The expected addition of new inventory with a shelf life exceeding the shelf life of inventory on hand caused the Company to reassess its selling strategy for the inventory on hand. As a result, in the six month period ended March 31, 2007, the Company established a reserve of \$1.1 million of the on-hand DELATESTRYL inventory that it believes is in excess of what can be sold before reaching a shelf life limitation and recorded the charge to cost of revenues. The Company has classified \$1,387,000 of DELATESTRYL inventory, net of the reserve, as noncurrent as of March 31, 2007.

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*D. Basic and Diluted Loss per Common Share*

The calculation of basic earnings per share for the three months ended March 31, 2007 and March 31, 2006, excludes unvested restricted stock with service-based vesting criteria of 265,900 shares and 215,900 shares, respectively.

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

During the three month period ended March 31, 2006, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 because the effect of their conversion would be antidilutive and (ii) options to purchase 4,607,000 shares of Common Stock at prices ranging from \$5.88 to \$20.13 with expiration dates ranging up to March 27, 2016 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended March 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) options to purchase 7,390,000 shares of Common Stock at prices ranging from \$1.22 to \$5.83 with expiration dates ranging up to February 13, 2016; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (iii) warrants to purchase 10,000 shares of Common Stock with an exercise price of \$6.19 and with an expiration date of July 17, 2006; and (iv) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,250 contingently issuable shares.

During the six month period ended March 31, 2007, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 because the effect of their conversion would be antidilutive and (ii) options to purchase 1,182,000 shares of Common Stock at prices ranging from \$6.85 to \$8.72 with expiration dates ranging up to March 26, 2017 because their exercise price exceeded the average market price during the period. Additionally, during the six month period ended March 31, 2007, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 11,100,000 shares of Common Stock at prices ranging from \$1.22 to \$6.72 with expiration dates ranging up to March 19, 2017; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iii) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 255,750 to 426,250 contingently issuable shares.

During the six month period ended March 31, 2006, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 because the effect of their conversion would be antidilutive and (ii) options to purchase 5,020,000 shares of Common Stock at prices ranging from \$4.94 to \$20.13 with expiration dates ranging up to March 27, 2016 because their exercise price exceeded the average market price during the period. Additionally, during the six month period ended March 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) options to purchase 6,972,000 shares of Common Stock at prices ranging from \$1.22 to \$4.42 with expiration dates ranging up to November 29, 2015; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iii) warrants to purchase 10,000 shares of Common Stock with an exercise price of \$6.19 and with an expiration date of July 17, 2006; and (iv) unvested restricted stock with service-based vesting criteria of 215,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 210,750 to 351,250 contingently issuable shares.

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

*E. Comprehensive Loss*

Comprehensive loss for the three and six months ended March 31, 2007 and 2006 is as follows:

|  | Three Months Ended March 31, |                        | Six Months Ended March 31, |                        |
|--|------------------------------|------------------------|----------------------------|------------------------|
|  | 2007                         | 2006                   | 2007                       | 2006                   |
| Net loss                                     | \$ (12,439,000)              | \$ (11,226,000)        | \$ (22,738,000)            | \$ (23,156,000)        |
| Change in unrealized net gain on investments |                              | 1,000                  |                            | 4,000                  |
| <b>Comprehensive loss</b>                    | <b>\$ (12,439,000)</b>       | <b>\$ (11,225,000)</b> | <b>\$ (22,738,000)</b>     | <b>\$ (23,152,000)</b> |

*F. Agreements**Madaus*

In November 2006, the Company entered into several agreements with Madaus, licensor of SANCTURA to the Company: (i) a License and Supply Agreement and (ii) an amendment to its original license agreement with Madaus, collectively (the Madaus Agreements). Under the Madaus Agreements, the Company agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007, (b) license to Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the Madaus Territory) except Canada, Japan, Korea and China (the Joint Territory), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by the Company in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time, (e) provide development committee support for a defined period and (f) provide future know-how to Madaus.

In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from the Company at cost plus a fee based on the number of SANCTURA XR capsules sold by them in the Madaus Territory and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments will represent royalty and milestone payments due to Supernus Pharmaceuticals, Inc. (formerly Shire Laboratories Inc.) (Supernus) from Indevus. Indevus signed an exclusive agreement with Supernus in March 2003 to develop extended release formulations of SANCTURA. The Company and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country.

The Madaus Agreements have been combined for accounting purposes and the Company evaluated the multiple deliverables in accordance with the provisions of EITF 00-21. As the Company was unable to determine the stand alone value of the delivered items and obtain verifiable objective evidence to for the fair value of the undelivered elements, the Company concluded there was a single unit of accounting.

The Company is currently unable to determine the term of its performance obligation to provide future know-how under the Madaus Agreements. The Company will recognize revenue to the extent of direct costs, limited to the amount of cash received or receivable, as long as the overall arrangement is determined to be profitable. Profit under the Madaus Agreements and payments received in advance of revenue recorded will be recorded as deferred revenue until the earlier of (i) when the Company can meet the criteria for separate recognition of each element under EITF 00-21 or (ii) after the Company has fulfilled all of its contractual obligations under the arrangement.

In addition, the Company will evaluate payments made by the Company to Madaus in accordance with the provisions of EITF 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products), to determine whether future payments to Madaus will be recognized as a reduction of revenue or a cost of sales.

*Novexel*

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In December 2006, the Company licensed its know-how related to aminocandin to Novexel, SA ( Novexel ) for an upfront payment of \$1,500,000 and potential future development milestones and royalties on net sales (the Novexel Agreement ). During the three and six months ended March 31, 2007, the \$1,500,000 upfront payment was recognized as

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contract and license fee revenue pursuant to the Company's completion of its obligations under the Novoxel Agreement. Immediately prior to the execution of the Novoxel Agreement, Aventis SA (Aventis), the Company's original licensor of aminocandin to Indevus, assigned the agreement between Aventis and Indevus to Novoxel. Effective as of the date of the Novoxel Agreement, the Company entered into a termination agreement with Novoxel terminating the original agreement between Aventis and Indevus, thereby alleviating the Company from any further development or financial obligation relating to aminocandin. Pursuant to the Novoxel Agreement, Novoxel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin.

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

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

At March 31, 2007, the Company had an accrued liability of approximately \$539,000 for Redux-related expenses, including legal expenses. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at March 31, 2007. To the extent amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

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



**Table of Contents***H. Other*

Accrued expenses consisted of the following:

|                                    | <b>March 31, 2007</b> | <b>September 30, 2006</b> |
|------------------------------------|-----------------------|---------------------------|
| Clinical and sponsored research    | \$ 7,245,000          | \$ 3,889,000              |
| Professional fees                  | 2,722,000             | 1,402,000                 |
| Compensation related               | 2,500,000             | 2,836,000                 |
| Milestone payment                  | 1,500,000             |                           |
| Manufacturing and production costs | 1,187,000             | 1,266,000                 |
| Redux related                      | 539,000               | 559,000                   |
| Other                              | 1,077,000             | 1,074,000                 |
|                                    | <b>\$ 16,770,000</b>  | <b>\$ 11,026,000</b>      |

Property and equipment at March 31, 2007 and September 30, 2006 are shown net of accumulated depreciation of \$1,702,000 and \$1,572,000, respectively.

On April 17, 2007 the stockholders of the Company voted to approve an increase of 80,000,000 shares of authorized common stock, an increase of 3,000,000 shares available to grant under the Company's 2004 Equity Incentive Plan, and an increase of 250,000 shares available to grant under the 1995 Employee Stock Purchase Plan.

*I. Recent Accounting Pronouncements*

In June 2006, the FASB issued EITF Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation)*. This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company's adoption of EITF No. 06-3 did not have a material impact on its financial statements. The Company adopted this provision in the interim period ended March 31, 2007 using the gross presentation method; this adoption did not have a material effect on the financial statements of the Company.

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

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, which is effective for fiscal years ending after November 15, 2006. SAB 108 provides interpretive guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. The Company does not expect the adoption of SAB 108 to have a material impact on its consolidated financial statements.

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007 or the Company's 2009 fiscal year. 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 still evaluating the implications of this standard, but does not currently expect it to have a significant impact.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115* (*SFAS No. 159*). SFAS No. 159 permits entities to choose to measure many financial instruments and

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certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is evaluating the impact that the adoption of SFAS No. 159 will have on its consolidated results of operations and financial condition.

**Table of Contents***J. Subsequent Events**Acquisition of Valera Pharmaceuticals, Inc.*

On April 18, 2007, the Company completed the acquisition of Valera Pharmaceuticals, Inc. ( Valera ), a specialty-pharmaceutical company focused on the development and commercialization of urology and endocrinology products and currently marketing VANTAS for advanced prostate cancer. At the time of the acquisition, SUPPRELIN LA, for central precocious puberty, was in development awaiting FDA action on a previously filed New Drug Application ( NDA ). Valera also has multiple products in clinical development including VALSTAR for the treatment of BCG-refractory bladder cancer, an octreotide implant for the treatment of acromegaly (giantism) and a biodegradable ureteral stent for patients being treated for kidney stones. The Company acquired Valera in a tax-free stock-for-stock merger valued at approximately \$129,700,000, plus contingent stock rights (each a CSR ) relating to three Valera product candidates in development at the time of acquisition.

Under the terms of the merger agreement, each share of Valera common stock was exchanged for 1.1337 shares of Indevus Common Stock. In aggregate, approximately 17,700,000 shares of Indevus common stock were issued pursuant to the merger agreement. In addition, each Valera shareholder received three CSRs per Valera share, relating to three Valera products in various stages of development. One CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of SUPPRELIN LA and the availability of sufficient launch quantities, one CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of a biodegradable ureteral stent and one CSR is convertible into \$1.50 of Indevus common stock upon FDA approval of an octreotide implant. The Indevus share price during the ten day period preceding each milestone achievement will determine the number of Indevus shares into which each CSR will become convertible. The CSRs convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of SUPPRELIN LA and within five years of the closing of the merger in the case of the biodegradable ureteral stent and the octreotide implant. The consideration paid upon conversion of the CSRs when each milestone is achieved will be recorded as additional purchase price and will increase goodwill. If all CSR milestones are achieved, the Company would issue common stock totaling approximately \$56,600,000 in value (See discussion below on FDA approval of SUPPRELIN LA for additional information).

The acquisition will be accounted for using the purchase method of accounting. Assets and liabilities assumed will be recorded at their fair values as of the date of acquisition, while the results of operations of Valera will be included in the consolidated results of operations of the Company from the date of acquisition. The following represents the preliminary purchase price allocation:

|  |                       |
|--|-----------------------|
| Net tangible assets acquired           | \$ 27,890,000         |
| In-process research and development    | 40,000,000            |
| Identifiable intangible assets         | 32,050,000            |
| Goodwill                               | 29,770,000            |
| <b>Total preliminary consideration</b> | <b>\$ 129,710,000</b> |

The amount of purchase price to be allocated to in-process research and development ( IPR&D ) relates to products in various stages of development and which have not yet received FDA approval. The Company will reflect the estimated \$40,000,000 of IPR&D as expense in the three and nine month periods ended June 30, 2007.

Identifiable intangible assets acquired are comprised of one marketed product, VANTAS, and core technology. The purchase price allocated to these intangible assets acquired will be based on their estimated fair values at the date of acquisition. The weighted average amortization period of all identifiable intangible assets will be approximately 16 years.

The excess of purchase price over net tangible assets acquired, in-process research and development, and identifiable intangible assets will be recorded as goodwill.

*FDA Approval of SUPPRELIN LA*

On May 3, 2007, the Company received approval from the FDA to market SUPPRELIN LA, its product for the treatment of central precocious puberty (CPP), the premature onset of puberty in children. SUPPRELIN LA is a once-yearly implant which utilizes the Company's patented hydron implant technology. The implant is inserted subcutaneously in the inner aspect of the upper arm and is specifically designed to provide a continuous release of approximately 65mcg/day over 12 months of the gonadotropin releasing hormone (GnRH) agonist, histrelin.

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As a result of the FDA approval of SUPPRELIN LA and the Company's possession of a specified amount of inventory of commercially sellable units, each CSR relating to SUPPRELIN LA became convertible into 0.141 shares of Indevus common stock. The Company anticipates that approximately 2,300,000 shares of its common stock, in aggregate, will be issued to the holders of the SUPPRELIN LA CSRs assuming the satisfaction of the applicable conversion requirements set forth in the agreement governing the CSRs.

### *K. Liquidity*

The Company believes its current and expected cash resources are sufficient to fund its operations through November 2007. In addition, we may receive an approximately \$35,000,000 payment from Esprit upon FDA approval of SANCTURA XR. If such payment from Esprit is received, the Company believes it will have sufficient capital to fund planned operations of the Company through March 2008. FDA approval may occur as early as August 2007, although there can be no assurance that FDA approval can be obtained. If we do not receive the \$35,000,000 payment from Esprit, we would need to obtain additional funding prior to November 2007 through corporate collaborations, strategic combinations or public or private equity or debt financing or a combination of such alternatives.

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

Statements in this Form 10-Q that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (tospium chloride tablets), SANCTURA XR (once-daily SANCTURA), and NEBIDO® (testosterone undecanoate) and VANTAS® (histrelin implant for prostate cancer); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux-related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and trends and do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company's Form 10-K for the fiscal year ended September 30, 2006. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, VALSTAR® and SUPPRELIN LA; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS and VALSTAR; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; failure to acquire and develop additional product candidates; changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL® and any future products; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; the risk that the businesses of Indevus and Valera will not be integrated successfully following the merger in April 2007; the risk that the cost savings and any other synergies from the merger may not be fully realized or may take longer to realize than expected; market acceptance for the merger and approved products; risks of regulatory review and clinical trials; disruption from the merger making it more difficult to maintain relationships with customers, employees or suppliers; competition and its effect on pricing, spending, third-party relationships and revenues; our reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; the effect of changes in governmental regulations 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, 2006. 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® for overactive bladder, which we co-promote with our partner Esprit Pharma, Inc., VANTAS® for advanced prostate cancer, and DELATESTRYL® (testosterone enanthate) for the treatment of male hypogonadism, all of which are currently marketed, as well as SUPPRELIN®-LA, which was recently approved for central precocious puberty. We currently market our products through an approximately 100-person specialty sales force and we have ten product candidates in development. Our development pipeline contains multiple compounds within our core therapeutic areas in addition to several partnered or partnerable programs. The most advanced compounds in development include SANCTURA XR, the once-daily formulation of SANCTURA, VALSTAR® for bladder cancer, NEBIDO® for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted pathogens, and pagoclone for stuttering.

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Effective April 18, 2007, we completed our acquisition of Valera Pharmaceuticals, Inc. ( Valera ) following the approval of the transaction by the stockholders of both Indevus and Valera. As a result of the acquisition, VANTAS, previously copromoted by Indevus, was added to Indevus marketed products and several compounds were added to our development pipeline, including VALSTAR, an octreotide implant for the treatment of acromegaly and a biodegradable ureteral stent for patients being treated for kidney stones. Each holder of Valera's common stock issued and outstanding immediately prior to the effective time of the merger, other than dissenting shares, if any, received 1.1337 shares of Indevus common stock for each share of Valera common stock resulting in the issuance of approximately 17,700,000 Indevus shares. In addition, Valera stockholders received three contingent stock rights (each a CSR ) for each share of Valera common stock. The CSRs will become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock upon the achievement of particular milestones with respect to three Valera product candidates in development SUPPRELIN LA (see below), a ureteral stent and an octreotide implant. The Indevus share price in the ten day period preceding each milestone achievement will determine the number of Indevus shares into which each CSR will become convertible. The CSRs convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of SUPPRELIN LA and within five years of the closing of the merger in the case of the biodegradable ureteral stent and the octreotide implant. As a result of the FDA approval of SUPPRELIN LA on May 3, 2007 and our possession of a specified amount of inventory of commercially sellable units which satisfies the condition under the contingent stock rights agreement related to such compound entered into in connection with the merger of Valera, we anticipate that approximately 2,300,000 shares of our common stock, in aggregate, valued at approximately \$16,500,000, will be issued to the holders of the SUPPRELIN LA CSRs assuming the satisfaction of the applicable conversion requirements set forth in the related agreement. If the CSR milestones relating to the ureteral stent and the octreotide implant are achieved, we would issue additional shares of common stock valued at approximately \$40,100,000.

**Recent Product Developments****SANCTURA XR**

In October 2006, we submitted an NDA to the FDA seeking approval for SANCTURA XR to treat patients with overactive bladder. As a result of the submission of the NDA, we received a \$10,000,000 milestone payment from Esprit, our co-promotion partner for SANCTURA and SANCTURA XR in the United States.

In November 2006, we entered into (i) a License and Supply Agreement and (ii) an amendment to an original licensing agreement with Madaus GmbH, or Madaus (the Madaus Agreements ). Under the Madaus Agreements, we agreed to (a) purchase from Madaus all required trospium active pharmaceutical ingredient through November 2007 (b) license to Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fixed fee based on the number of capsules of SANCTURA XR sold by us in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time (e) provide development committee support for a defined period and (f) provide future know-how to Madaus. In exchange, Madaus (a) waived all rights to manufacture SANCTURA XR, (b) will purchase SANCTURA XR from us at cost plus a fee based on the number of SANCTURA XR capsules sold in the Madaus Territory, and (c) will make payments upon the achievement of certain commercial milestones and royalties based on future sales of SANCTURA XR in the Madaus Territory. Certain of the milestone and royalty payments we will receive represent royalty and milestone payments due to Supernus Pharmaceuticals, Inc., or Supernus, formerly Shire Laboratories, Inc., from us under the development and license agreement we entered into with Supernus in March 2003. We and Madaus will share the economics of development and commercialization in the countries in the Joint Territory. If either party decides not to pursue development and commercialization of SANCTURA XR in any country in the Joint Territory, the other party has the right to develop and commercialize SANCTURA XR in that country.

In November 2006, we entered into the API Supply Agreement with Helsinn Chemicals SA and Helsinn Advanced Synthesis SA ( Helsinn ) (the Helsinn Agreement ) whereby Helsinn agreed to supply trospium active pharmaceutical ingredient to us. Trospium active pharmaceutical ingredient is used in the production of SANCTURA XR. The term of the Helsinn Agreement is seven years and contains certain minimum purchase requirements.

**NEBIDO**

In October 2006, we entered into an agreement with Schering AG ( Schering ) under which we finalized terms of our July 2005 license for the manufacture and the supply of NEBIDO from Schering. Pursuant to the terms of this agreement, Schering agreed to manufacture and supply us with all of our requirements for NEBIDO. In addition, we are obligated to purchase certain minimum quantities from Schering during the term of this agreement.

**SUPPRELIN LA**

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On May 3, 2007, we received approval from the FDA for SUPPRELIN LA, our product for the treatment of central precocious puberty (CPP), the premature onset of puberty in children. SUPPRELIN LA is a once-yearly implant which utilizes our patented hydron implant technology. The implant is inserted subcutaneously in the inner aspect of the upper arm and is specifically designed to provide a continuous release of approximately 65mcg/day over 12 months of the gonadotropin releasing hormone (GnRH) analog histrelin.

### AMINOCANDIN

In December 2006, we licensed our know-how related to aminocandin to Novexel, SA ( Novexel ) for an upfront payment of \$1,500,000 and potential future development milestones and royalties on net sales (the Novexel Agreement ). Immediately prior to the execution of the Novexel Agreement, Aventis SA, the original licensor of aminocandin to us, assigned the agreement between Aventis and Indevus to Novexel. Effective as of the date of the Novexel Agreement, we entered into a termination agreement with Novexel terminating the original agreement between Aventis and ourselves, thereby alleviating us from any further development or financial obligation relating to aminocandin. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial

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obligations relating to aminocandin. We recognized the \$1,500,000 upfront payment as contract and license fee revenue during the three months ended March 31, 2007 upon completion of certain obligations related to the transfer of our aminocandin know-how.

**ALKS 27**

In January 2007, we announced our joint collaboration with Alkermes, Inc. for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of COPD. Trospium chloride is the active ingredient in SANCTURA. The announcement of this collaboration followed the completion of feasibility work, preclinical studies and a Phase I study in healthy volunteers. Preliminary results from the Phase I study showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed. Pursuant to the collaboration arrangement, we and Alkermes will share equally in all costs of development and commercialization of ALKS 27 on a worldwide basis. In April 2007, we initiated with Alkermes a Phase IIa clinical study to assess the safety, tolerability, pharmacokinetics and efficacy of single doses of ALKS 27. The study is also designed to further define the clinical profile of ALKS 27 in patients with COPD.

**VALSTAR**

In April 2007, we submitted a Supplemental New Drug Application (sNDA) to the FDA seeking approval to reintroduce VALSTAR in the United States. 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). VALSTAR was removed from the market in 2002 due to manufacturing issues involving the stability of an excipient (an inactive ingredient). We believe the stability issues have been resolved through the development of an improved manufacturing process.

**Critical Accounting Policies and Estimates**

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

*Expected Term of the SANCTURA Agreement and Deferred Revenue*

In April 2004, we entered into the license, commercialization and supply agreement with PLIVA d.d. ( PLIVA ), through its specialty-branded subsidiary, Odyssey, for the U.S. commercialization of SANCTURA (the SANCTURA Agreement ), as amended by the Amendment and Consent agreement we entered into effective as of July 1, 2005, with PLIVA and Esprit, pursuant to which we amended certain provisions of the SANCTURA Agreement and consented to the acquisition by Esprit of the rights to market SANCTURA in the U.S. from PLIVA and the assumption by Esprit of PLIVA's obligations under the SANCTURA Agreement. We currently estimate the expected term of the SANCTURA Agreement to be twelve years from the commencement of the agreement. As used in this Form 10-Q, except if the context indicates otherwise, all references to the SANCTURA Agreement shall mean the agreement as amended by the Amendment and Consent.

We have recorded \$171,000,000 of initial and milestone payments received pursuant to the SANCTURA Agreement as deferred revenue and are amortizing each component into revenue using the contingency-adjusted method over the estimated remaining duration of the SANCTURA Agreement commencing on the date such payments are earned. The balance of deferred revenue under the SANCTURA Agreement at March 31, 2007 is \$128,249,000. We believe the estimated term of the SANCTURA Agreement is a significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet. We will reevaluate our estimate of the expected term of the SANCTURA Agreement when new information is known that could affect this estimate. If we change our estimate of the duration of the SANCTURA Agreement in the future and extend or reduce our estimate of its duration, we would decrease or increase, respectively, the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue.



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### *Insurance Claim Receivable*

As of March 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 March 31, 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.

### *Redux-Related Liabilities*

At March 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 March 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.

### *Revenue Recognition Policy*

Product revenue consists primarily of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by us to Madaus GmbH ( Madaus ) for SANCTURA. Product revenue also includes revenue earned from shipments of DELATESTRYL, acquired in January 2006 from Savient Pharmaceuticals, Inc. ( Savient ). 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. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

Contract and license fee revenue consists of revenue from contractual initial and milestone payments received from partners, including amortization of deferred revenue from contractual payments, sales force subsidies, and grants from agencies supporting research and development activities.

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, funding of research and development, payments based upon achievement of certain milestones and royalties on net product sales. Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. In multiple element arrangements where we have continuing performance obligations, license fees are recognized together with any up-front payment over the term of the arrangement as we complete our performance obligations, unless the delivered technology has stand alone value to the customer and there is objective and reliable evidence of fair value of the undelivered elements in the arrangement. We record such revenue as contract and license fee revenue.

Revenues from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the



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milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. We record such revenue as contract and license fee revenue.

Under the SANCTURA Agreement, the initial and subsequent milestone payments, once earned, are recognized as contract and license fee revenue using the contingency-adjusted performance model. Under this model, when a milestone is earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the SANCTURA Agreement to the time the milestone is earned over the estimated duration of the SANCTURA Agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated duration of the SANCTURA Agreement.

Multiple element arrangements are evaluated pursuant to Emerging Issues Task Force ( EITF ) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. In the case of an arrangement where it is determined there is a single unit of accounting, all cash flows from the arrangement are considered in the determination of all revenue to be recognized. Additionally, pursuant to the guidance of Securities and Exchange Commission SAB No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangements.

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

### *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.

### *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 includes 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. At March 31, 2007 and September 30, 2006, all investments held were classified as available-for-sale. 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.

### *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 it receives approval from the FDA for a new product, at which time we commence capitalization of costs relating to that product.

## **Results of Operations**

Our net loss increased \$1,213,000, or 11%, to \$(12,439,000), or \$(0.22) per share, basic, in the three month period ended March 31, 2007 from \$(11,226,000), or \$(0.24) per share, basic, in the three month period ended March 31, 2006 and decreased \$418,000, or 2%, to \$(22,738,000), or \$(0.41) per share, basic, in the six month period ended March 31, 2007 from \$(23,156,000), or \$(0.49) per share, basic, in the six month period ended March 31, 2006. The increased net loss in the three month period ended March 31, 2007 is primarily the result of higher operating expenses including costs associated with our NEBIDO development programs.

Total revenues decreased \$3,198,000, or 22%, to \$11,224,000 in the three month period ended March 31, 2007 from \$14,422,000 in the three month period ended March 31, 2006 and increased \$979,000, or 4%, to \$24,375,000 in the six month period ended March 31, 2007 from \$23,396,000 in the six month period ended March 31, 2006. The decrease in the three month period ended March 31, 2007 is primarily due to a

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decrease of SANCTURA product sales of \$4,282,000 in 2007 and \$1,266,000 of one-time contract and license fee revenue from the amended bucindol license agreement recognized during the three months ended March 31, 2006. These reductions were partially offset by increased SANCTURA royalty revenue of \$703,000 and license fees of \$1,500,000 received from Novoxel pursuant to the Novoxel Agreement. The increase in total revenues in the six month period ended March 31, 2007 is attributed primarily to increases in contract and license fee revenues of \$2,697,000 resulting from amortization of deferred revenue related to a \$10,000,000 milestone payment received from Esprit in October 2006, \$1,500,000 in license fees recognized pursuant to the Novoxel Agreement and increased SANCTURA royalty revenue of approximately \$1,406,000. Decreased SANCTURA product revenue of approximately \$3,833,000 during the six months ended March 31, 2007 and the one-time recognition of \$1,266,000 from the amended bucindol license agreement in 2006 partially offset these increases.

Product revenues decreased \$3,987,000, or 54%, to \$3,455,000 in the three month period ended March 31, 2007 from \$7,442,000 in the three month period ended March 31, 2006 and decreased \$2,159,000, or 20% to \$8,712,000 in the six month period ended March 31, 2007 from \$10,871,000 in the six month period ended March 31, 2006. We did not record any SANCTURA product sales during the three months ended March 31, 2007 compared to \$4,282,000 in SANCTURA product sales for the three months ended March 31, 2006. Sales of SANCTURA decreased \$3,833,000 to \$1,883,000 in the six month period ended March 31, 2007 from \$5,716,000 in the six month period ended March 31, 2006. Sales of

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SANCTURA to Esprit, our marketing partner, are dependent upon the timing of our partner's orders which can vary from period to period. Esprit has informed us that it will significantly reduce its orders for SANCTURA during the remainder of our current fiscal year as it manages its SANCTURA inventory closely in anticipation of the FDA's approval of our once-daily product, SANCTURA XR. We therefore anticipate minimal SANCTURA product sales for the remainder of our current fiscal year. Royalties from SANCTURA increased \$703,000 to \$2,461,000 in the three month period ended March 31, 2007 from \$1,758,000 in the three month period ended March 31, 2006 and increased \$1,406,000 to \$4,922,000 in the six month period ended March 31, 2007 from \$3,516,000 in the six month period ended March 31, 2006, respectively. Royalties in the fiscal 2007 and 2006 periods reflected the minimum royalties due from Esprit for SANCTURA. The minimum royalties increased on an annual basis from \$5,625,000 to \$7,875,000 effective July 1, 2006. We expect royalty revenue from SANCTURA in fiscal 2007 will continue to reflect such minimum royalties, which will increase to \$10,500,000 annually for the royalty year commencing July 1, 2007. Esprit's minimum royalty obligation will expire in June 2008. Additionally, product revenue in the three and six month periods ended March 31, 2007 included \$660,000 and \$1,290,000, respectively, of net sales of DELATESTRYL. We commenced selling DELATESTRYL in January 2006.

Contract and license fee revenues increased \$789,000, or 11%, to \$7,769,000 in the three month period ended March 31, 2007 from \$6,980,000 in the three month period ended March 31, 2006 and \$3,138,000, or 25%, to \$15,663,000 in the six month period ended March 31, 2007 from \$12,525,000 in the six month period ended March 31, 2006. Sales force subsidies pursuant to our SANCTURA agreement with Esprit were approximately \$2,249,000 and \$2,188,000 in the three months ended March 31, 2007 and 2006, respectively, and \$4,498,000 and \$4,375,000 in the six month periods ended March 31, 2007 and 2006, respectively. Contract and license fee revenues during the three and six months ended March 31, 2007 also includes approximately \$441,000 in revenue earned from our copromotion and marketing services agreement with Valera that commenced in December 2006 pursuant to which our sales force and Valera co-promoted VANTAS in the United States. The copromotion and marketing services agreement with Valera terminated concurrent with our acquisition of Valera effective April 18, 2007. Also included in contract and license fee revenue was \$3,562,000 and \$3,354,000 from amortization of deferred revenue in the three month periods ended March 31, 2007 and 2006, respectively. Amortization of deferred revenue in the six months ended March 31, 2007 and 2006 was \$9,208,000 and \$6,708,000, respectively. The \$2,500,000 increase in amortization of deferred revenue for the six months ended March 31, 2007 is related to the \$10,000,000 milestone received from Esprit in October 2006 pursuant to our filing the SANCTURA XR NDA. During the three and six months ended March 31, 2007, increased license fee revenue of approximately \$1,500,000 received from Novoxel pursuant to the Novoxel Agreement was partially offset by one-time recognition of \$1,266,000 revenue recognized during the three and six months ended March 31, 2006 from our amended bucindol license agreement.

Cost of product revenue decreased \$4,506,000, or 78%, to \$1,274,000 in the three month period ended March 31, 2007 from \$5,780,000 in the three month period ended March 31, 2006 and decreased \$2,100,000, or 27%, to \$5,550,000 in the six month period ended March 31, 2007 from \$7,650,000 in the six month period ended March 31, 2006. We did not ship SANCTURA product to Esprit during the three months ended March 31, 2007, resulting in a \$4,086,000 reduction in cost of product revenues compared to the three months ended March 31, 2006. During the six months ended March 31, 2007, lower shipments of SANCTURA to Esprit reduced our cost of product revenues by \$3,338,000 compared to the six month period ended March 31, 2006. Partially offsetting this decrease in cost of product revenue in the six month period ended March 31, 2007 was a \$1,100,000 reserve established in our first fiscal quarter of 2007 for excess DELATESTRYL inventory (see Note C).

Research and development expense decreased \$162,000, or 2%, to \$9,272,000 in the three month period ended March 31, 2007 from \$9,434,000 in the three month period ended March 31, 2006 and decreased \$563,000, or 3%, to \$19,191,000 in the six month period ended March 31, 2007 from \$19,754,000 in the six month period ended March 31, 2006. These decreases are primarily due to decreased external product development costs of approximately \$549,000 and \$1,337,000 in the three and six month periods ended March 31, 2007, respectively. External development costs related to trospium development decreased approximately \$2,416,000 and \$4,218,000 in the three and six month periods ended March 31, 2007, and related primarily to a reduction in expense for the Phase III clinical development program for SANCTURA XR initiated in September 2005 and ended in March 2007. Pagoclone external development costs related primarily to our Phase II clinical trial for stuttering decreased approximately \$158,000 and \$446,000 in the three and six month periods ended March 31, 2007. External development costs related to aminocandin development also decreased by approximately \$68,000 and \$437,000 during the three and six month periods ended March 31, 2007 as a result of our decision to out-license the worldwide rights to aminocandin to Novoxel in December 2006. Partially offsetting these decreased external development costs are increased NEBIDO external development costs of approximately \$2,377,000 and \$3,818,000 in the three and six month periods ended March 31, 2007, respectively, related to the clinical trial that commenced during our fiscal quarter ended March 31, 2006. Offsetting a portion of the reduced external development costs during the three and six months ended March 31, 2007 were increases in employee compensation related expenses of approximately \$238,000 and \$484,000, respectively, primarily as a result of hiring new employees.

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Marketing, general and administrative expense increased \$3,179,000, or 33%, to \$12,687,000 in the three month period ended March 31, 2007 from \$9,508,000 in the three month period ended March 31, 2006 and increased \$3,874,000, or 22%, to \$21,690,000 in the six month period ended March 31, 2007 from \$17,816,000 in the six month period ended March 31, 2006. Marketing expense increased \$2,466,000, or 45%, to \$8,004,000 in the three month period ended March 31, 2007 from \$5,538,000 in the three month period ended March 31, 2006 and \$2,712,000, or 27%, to \$12,823,000 in the six month period ended March 31, 2007 from \$10,111,000 in the six month period ended March 31, 2006. The increase in marketing expense in the three and six month periods ended March 31, 2007 include expense of approximately \$1,200,000 and \$1,600,000, respectively, for NEBIDO and approximately \$400,000 related to our January 2007 VANTAS copromotion program. Compensation-related expenses, including FAS 123R stock compensation expense, increased by approximately \$532,000 and \$780,000 during the three and six months ended March 31, 2007. We expect to incur significant expenses in fiscal 2007 related to the promotion of VANTAS and SUPPRELIN LA including the launch of SUPPRELIN LA.

General and administrative expense increased \$742,000, or 19%, to \$4,712,000 in the three month period ended March 31, 2007 from \$3,970,000 in the three month period ended March 31, 2006 and increased \$1,190,000, or 15%, to \$8,895,000 in the six month period ended March 31, 2007 from \$7,705,000 in the six month period ended March 31, 2006. The increase during the three and six month periods included approximately \$100,000 and \$500,000, respectively, from increased compensation-related expenses. During the three and six months ended March 31, 2007, we also incurred approximately \$200,000 of expense related to our proposed merger with Valera Pharmaceuticals, including costs related to preparations for our special shareholder meeting held in April 2007. As of March 31, 2007 we have also recorded prepaid assets of approximately \$3,113,000 primarily representing legal, accounting and valuation services incurred in relation to the Valera acquisition. These costs, included in prepayments and other current assets in our balance sheet at March 31, 2007, will be included in the allocation of the Valera purchase price as of the date of the merger. During the three and six months ended March 31, 2006, we also recorded a credit of approximately \$300,000 resulting from the settlement of our lease obligation for our prior office facility.

Investment income increased \$61,000, or 8%, to \$863,000 in the three month period ended March 31, 2007 from \$802,000 in the three month period ended March 31, 2006 and increased \$215,000, or 13%, to \$1,903,000 in the six month period ended March 31, 2007 from \$1,688,000 in the six month period ended March 31, 2006.

Interest expense of \$1,293,000 in the three month periods and \$2,585,000 in the six month periods relates to our \$72,000,000 of 6.25% Convertible Senior Notes due 2008 (the Convertible Notes ). Annual interest expense is expected to be approximately \$5,200,000, which includes approximately \$700,000 of amortization of debt issuance costs.

We expect to report losses from our consolidated operations for fiscal 2007.

## **Liquidity and Capital Resources**

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

At March 31, 2007 we had consolidated cash and cash equivalents of \$59,009,000 compared to consolidated cash, cash equivalents and marketable securities of \$76,125,000 at September 30, 2006. This decrease of \$17,116,000 is primarily the result of net cash used in operating activities of \$14,623,000 and prepaid acquisition costs of \$3,113,000 related to Valera (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. In particular, we are investing in the development of NEBIDO and will invest in regulatory activities related to a NEBIDO NDA if the currently ongoing pharmacokinetic study is successful.

We will require additional funds or corporate collaborations for the development and commercialization of our 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 April 18, 2007 we completed our acquisition of Valera. In addition to our \$59,009,000 of cash and cash equivalents at March 31, 2007, there are certain events that could add significant additional cash resources to fund the operations of the combined company. Among these events, we may receive, upon FDA approval of SANCTURA XR, a payment of approximately \$35,000,000 from Esprit, payable at Esprit's option, which would add to our cash resources. FDA approval may occur as early as August 2007, although there can be no assurance that FDA approval can be obtained. We believe that with this \$35,000,000 payment from Esprit, our existing cash resources will be sufficient to fund planned operations of the combined companies through March 2008. If we do not receive the \$35,000,000 payment from Esprit, we would need to obtain additional funding prior to November 2007 through corporate collaborations, strategic combinations or public or private equity or debt financing

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or a combination of such alternatives. Although we believe we will receive the \$35,000,000 payment if the FDA approves the SANCTURA XR NDA, or would otherwise be able to obtain additional capital to fund its operations, there can be no assurance that the \$35,000,000 payment from Esprit will be received or that additional capital can be obtained on favorable terms or at all. The failure to receive such payment or raise such funds would result in the need to significantly curtail our marketing activities and delay development efforts, which would have a material adverse effect on us.

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Our \$72,000,000 Convertible Notes become due in July 2008. All or a portion of the Convertible Notes are redeemable by us for cash at any time provided our Common Stock equals or exceeds 150% of the conversion price then in effect for a specified period, currently \$6.656 per share, and all of the Convertible Notes are subject to repurchase by us at the option of the Convertible Note holders if a change in control occurs. If the Convertible Notes are not converted to Common Stock by July 2008, we will be required to redeem them for cash.

There remains 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

We expect to continue to expend substantial additional amounts for the development of our products. In particular, we are continuing to expend substantial funds for NEBIDO and other development efforts, including SANCTURA XR. We are responsible for conducting and funding the development of SANCTURA XR. We could receive approximately \$35,000,000 in future payments contingent upon the approval of an NDA for SANCTURA XR. If Esprit provides notice to us no later than the approval date that it does not intend to proceed with the launch of SANCTURA XR, Esprit will not have an obligation to pay the development milestone of approximately \$35,000,000 related to the FDA approval of the NDA for SANCTURA XR or the \$20,000,000 long-term commercialization milestone and the U.S. rights to SANCTURA XR will revert to us.

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

Total research and development expenses incurred by us through March 31, 2007 on the major compounds currently being developed or marketed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: \$144,000,000 for SANCTURA and SANCTURA XR, \$26,000,000 for NEBIDO, \$20,000,000 for PRO 2000, \$7,000,000 for IP 751 and \$37,000,000 for pagoclone. In June 2002, we re-acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from March 31, 2007 through the preparation of an NDA for our major compounds currently being developed as follows: approximately \$4,000,000 for NEBIDO, \$14,000,000 for PRO 2000, approximately \$46,000,000 for IP 751 and approximately \$72,000,000 for pagoclone for stuttering. In December 2006, we entered into the Novexel Agreement whereby Novexel is now responsible for all future development, manufacturing, marketing and financial



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obligations relating to aminocandin. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development.

**Analysis of Cash Flows**

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

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

Net cash provided by financing activities of \$806,000 were the result of common stock issued from employee exercises of stock options and employee participation in our employee stock purchase plan during the six months ended March 31, 2007. We cannot predict if or when stock options will be exercised in the future.

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

The following chart summarizes our contractual payment obligations as of March 31, 2007. The Convertible Notes and license fees are reflected as liabilities on our Balance Sheet as of March 31, 2007. Operating leases are accrued and paid pursuant to the lease arrangement. Purchase obligations relate to research and development agreements and arrangements; portions of these amounts are reflected as accrued expenses on our Balance Sheet as of March 31, 2007.

| Contractual Obligations       | Payments due by Period |                      |                   |                         | Total                 |
|-------------------------------|------------------------|----------------------|-------------------|-------------------------|-----------------------|
|                               | Less than 1<br>Year    | 1-3 Years            | 3-5 Years         | Greater than 5<br>Years |                       |
| Convertible Notes             | \$                     | \$ 72,000,000        | \$                | \$                      | \$ 72,000,000         |
| Interest on Convertible Notes | 4,500,000              | 2,250,000            |                   |                         | 6,750,000             |
| Purchase obligations (1)      | 19,114,000             | 5,111,000            | 15,000            |                         | 24,240,000            |
| Operating leases              | 1,256,000              | 2,237,000            | 684,000           |                         | 4,177,000             |
| <b>Total</b>                  | <b>\$ 24,870,000</b>   | <b>\$ 81,598,000</b> | <b>\$ 699,000</b> | <b>\$</b>               | <b>\$ 107,167,000</b> |

(1) Relates primarily to agreements and purchase orders with contractors for the conduct of clinical trials and other research and development activities.

Pursuant to certain of our in-licensing arrangements, we will owe payments to our licensors upon achievement of certain development, regulatory and licensing milestones. We generally cannot predict if or when such events will occur. In fiscal 2006, we recorded a license payment obligation to Madaus and an intangible asset of \$1,500,000 in recognition of expected achievement of a contingent cumulative net sales milestone related to SANCTURA. We expect to pay the milestone when it is achieved, currently estimated to occur within the next twelve months.

Pursuant to our agreement with Madaus, we are committed to purchase from Madaus significant minimum quantities of bulk SANCTURA tablets during fiscal 2007 aggregating approximately \$3,900,000. In January 2007, Esprit informed us that it was significantly reducing its orders for SANCTURA during the remainder of our current fiscal year as they manage their SANCTURA inventory closely in anticipation of the FDA approval of our once-daily product, SANCTURA XR. Therefore we do not expect to satisfy our minimum purchase requirements under our supply agreement with Madaus and we expect to be subject to a minimum supply fee of a portion of the value of the unpurchased minimum quantities. Under our agreement with Esprit, Esprit will be responsible for any minimum supply fees payable to Madaus. Therefore we will not

incur a net loss as a result of the minimum supply fee.

Pursuant to our agreement with Savient whereby we acquired DELATESTRYL in January 2006, we assumed a commitment to purchase approximately \$1,100,000 of additional DELATESTRYL from a third-party supplier. As of

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September 30, 2006, we believed that the supplier had defaulted on its obligation under the purchase commitment to deliver the DELATESTRYL and concluded that we were no longer obliged by its assumed commitment, which the supplier disputed. We subsequently determined that it will be cost beneficial to settle the dispute with the supplier and as a result of negotiations have estimated that we will purchase an additional quantity of DELATESTRYL at a cost of approximately \$750,000 which we expect to pay before the end of calendar 2007.

The Helsinn Agreement contains certain minimum purchase requirements of trospium active pharmaceutical ingredient used in the production of SANCTURA XR. These requirements could commence in calendar 2009 if SANCTURA XR is approved prior to the end of calendar 2007.

The Schering Agreement contains certain minimum purchase requirements that would commence after the second year of sales of NEBIDO. Such minimums will be determined to be a percent of purchase we would make in the second year of sales. After the second year of sales, we will be able to determine such minimum purchase requirements.

Pursuant to a supply agreement for valrubicin, the active ingredient of VALSTAR, we are obligated to purchase \$1,000,000 of valrubicin annually for ten years commencing the year following FDA approval to sell VALSTAR. In April 2007, we filed an NDA for VALSTAR. If VALSTAR is approved by the FDA in 2007, this minimum purchase obligation will commence in 2008.

Pursuant to a consulting agreement with UBS Securities, our financial advisor in the Valera acquisition, we became obligated to pay UBS \$1,500,000 at the consummation of the acquisition.

**Other**

In June 2006, the FASB issued EITF Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation)*. This standard allows companies to present in their statements of income any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. We are currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

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

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, which is effective for fiscal years ending after November 15, 2006. SAB 108 provides interpretive guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. We do not expect the adoption of SAB 108 to have a material impact on our consolidated financial statements.

On September 15, 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to do so for recognition or disclosure purposes. The standard provides a common definition of fair value and is intended to make the measurement of fair value more consistent and comparable as well as improving disclosures about those measures. The standard is effective for financial statements for fiscal years beginning after November 15, 2007 or our 2009 fiscal year. This standard formalizes the measurement principles to be utilized in determining fair value for purposes such as derivative valuation and impairment analysis. We are still evaluating the implications of this standard, but does not currently expect it to have a significant impact.

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



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

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

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

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

Risk related to the Convertible Notes

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a \$1,000 Note by approximately \$75. 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 \$5. 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.

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**Item 4. Controls and Procedures**  
**Evaluation of Disclosure Controls and Procedures**

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

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 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 Wyeth's national class action settlement of diet drug claims and claimants alleging primary pulmonary hypertension. In addition, Wyeth agreed to fund all future legal costs related to our defense of Redux-related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure.

Up to the date of the AHP indemnity and release agreement, our defense costs were paid by, or subject to reimbursement to us from, our product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by us or our insurers.

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

*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

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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**

*The risk factors presented below amend and restate the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended September 30, 2006.*

*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, Item 2 Note Regarding Forward Looking Statements.*

#### **Risks Relating to the Merger between Indevus and Valera**

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

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 at one or both of the companies 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, diversion of management's attention, 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 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.

*In the event we do not effectively manage our expanded sales force, marketing and sales of VANTAS and SUPPRELIN LA, or development of the ureteral stent, octreotide implant or other products in development, operating results may be materially adversely affected.*

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As a result of the merger, we have increased the size of our specialty sales force, added Valera's VANTAS and SUPPRELIN LA to the products we currently sell and added the ureteral stent, octreotide implant, and other Valera product candidates in development, to our development pipeline. The expanded specialty sales force might be unable to successfully market and sell VANTAS, or the resources devoted to incorporating VANTAS could cause the combined company to less effectively market and sell our other products. In addition, our development team might not be able to obtain approval for the ureteral stent, octreotide implant, and the other Valera products in development. If we are unable to successfully market and sell VANTAS or obtain FDA approval for SUPPRELIN LA, the ureteral stent, octreotide implant, and the other Valera product candidates in development, it may have a material adverse effect on the combined company and, as a result, on the market price of our common stock.



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***If we are unable to retain key Indevus or Valera personnel, our business may suffer.***

The success of the merger will depend in part on our ability to retain sales, marketing, development, manufacturing and other personnel currently employed by Indevus and those key Valera employees who continue employment with Indevus. It is possible that these employees might decide not to remain with us. If key employees terminate their employment, or insufficient numbers of employees are retained to maintain effective operations, the combined company's sales, marketing or development activities might be adversely affected, management's attention might be diverted from successfully integrating Valera's operations to hiring suitable replacements, and the combined company's business might suffer. 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.

***Charges to earnings resulting from the application of the purchase method of accounting relating to the merger might adversely affect the market value of our common stock.***

In accordance with U.S. GAAP, the merger is being accounted for using the purchase method of accounting, which will result in charges to earnings that could have an adverse impact on the market value of our common stock. Under the purchase method of accounting, the total estimated purchase price will be allocated to Valera's net tangible assets, identifiable intangible assets or expense for research and development based on their fair values as of the date of completion of the merger. Any excess of the purchase price over those fair values will be recorded as goodwill. The combined company will incur additional amortization expense based on the identifiable amortizable intangible assets acquired pursuant to the merger agreement and their relative useful lives. Additionally, to the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, the combined company will be required to incur material charges relating to the impairment. These amortization and potential impairment charges could have a material impact on the combined company's results of operations.

We currently estimate that we will incur approximately \$2.0 million of incremental annual amortization expense after completion of the merger. Changes in earnings per share, as a result of this incremental expense, could adversely affect the trading price of our common stock.

***We will incur significant additional expenses in connection with the integration of the two businesses***

We expect to incur significant additional expenses in connection with the integration of the two businesses, including integrating personnel, geographically diverse operations, information technology systems, accounting systems, customers, and strategic partners of each company and implementing consistent standards, policies, and procedures, and may be subject to possible material write downs in assets and charges to earnings, which are expected to include severance pay and other costs.

***If Valera's former stockholders immediately sell our common stock received in the merger, they could cause our common stock price to decline.***

Our common stock issued in the merger is registered under the federal securities laws. As a result, those shares are available for resale in the public market. The number of shares of our common stock issued in connection with the merger to Valera's former stockholders, and immediately available for resale, was approximately 17,700,000 shares, or 31% of the number of outstanding Indevus common shares immediately prior to the merger. Valera's former stockholders may sell the stock they received immediately after the merger. If this occurs, or if other holders of our common stock sell significant amounts of our common stock, 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.

In addition, we have agreed to register approximately 6,200,000 shares 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 on a Registration Statement on Form S-3 to be filed by us within 30 days following the effective time of the merger. If SMH sells significant amounts of our common stock immediately after the resale registration statement is effective, the market price for our common stock could decline and it may make it more difficult for us to sell equity securities at a time and at a price we deem appropriate to raise funds through future offerings of common stock.

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*The market price of our common stock after the merger might be affected by factors different from those affecting the shares of Valera or Indevus currently.*

The businesses of Indevus and Valera differ somewhat and, accordingly, the results of operations of the combined company and the market price of the combined company's common stock might be affected by factors different from those currently affecting the independent results of operations of each of Indevus or Valera.

*We will need to raise additional financing following the merger*

We believe that our existing cash resources will be sufficient to fund our planned combined operations through November 2007. There are certain events that could add significant additional cash resources to fund the operations of the combined company. Among these events, we may receive, upon FDA approval of SANCTURA XR, a payment of approximately \$35,000,000 from Esprit, payable at Esprit's option, which would add to our cash resources. FDA approval may occur as early as August 2007, although there can be no assurance that FDA approval can be obtained. If we do not receive the \$35,000,000 payment from Esprit, we would need to obtain additional funding prior to November 2007 through corporate collaborations, strategic combinations or public or private equity or debt financing or a combination of such alternatives. Although we believe we will receive the \$35,000,000 payment if the FDA approves the SANCTURA XR NDA, or would otherwise be able to obtain additional capital to fund our operations, there can be no assurance that the \$35,000,000 payment from Esprit will be received or that additional capital can be obtained on favorable terms or at all. The failure to receive such payment or raise such funds would result in us significantly curtailing our marketing and operations and delay development efforts, which would have a material adverse effect on us.

## **Risks Relating to Our Business**

*We will be dependent on SANCTURA and VANTAS and the ability of Esprit Pharma, Inc. to perform its obligations with respect to SANCTURA.*

We will derive a substantial portion of our revenue from only two products. One is SANCTURA, a treatment for overactive bladder, which we co-promote with our marketing partner, Esprit Pharma, Inc., under an agreement referred to as the SANCTURA Agreement. The other is VANTAS, a product for the treatment of advanced prostate cancer, which was approved for commercial use in October 2004. We believe that revenues derived under the SANCTURA Agreement and from the sale of VANTAS will continue to account for a substantial portion of our revenue for the foreseeable future. We are highly dependent on Esprit for the commercialization and marketing of SANCTURA and for performance of its obligations under the SANCTURA Agreement. This includes our dependence on Esprit to devote sufficient resources to effectively market SANCTURA. The failure of Esprit to devote such resources, perform its obligations under this agreement, or to market SANCTURA, could adversely affect our business, financial condition and results of operations. Esprit is a private company whose ability to perform its obligations may be impacted by the success of SANCTURA and SANCTURA XR and its ability to raise funds. Because we do not have access to Esprit's financial statements and internal operating and financing plans, we are uncertain of Esprit's financial condition and therefore its ability to perform under its agreements which could materially adversely affect Indevus. In particular, if sales of SANCTURA do not increase, we are unlikely to derive royalties in excess of the minimum royalties under the SANCTURA Agreement and, after the minimum royalty period expires in June 2008, our royalty revenue may decrease substantially. Esprit is not obligated to purchase any minimum amount of SANCTURA from us. SANCTURA may suffer from generic penetration after the expiration of the market exclusivity period in May 2009, and competes with many once-daily and other formulations of products to treat overactive bladder. Our long-term success will be highly dependent on our ability to successfully develop, manufacture and commercialize SANCTURA XR, a once daily formulation of SANCTURA. If SANCTURA does not continue to achieve market acceptance or if Esprit provides notice to us that it does not intend to pay us the development milestone of \$35,000,000 due on FDA approval of SANCTURA XR causing the rights to SANCTURA XR to revert to us, then the financial situation and the marketing of SANCTURA XR may be adversely affected, and if our subsequent efforts to develop and market SANCTURA XR are unsuccessful, our business, financial condition and results of operations may be materially adversely affected. Further, our sales force subsidy for our co-promotion of SANCTURA and SANCTURA XR in the U.S. expires on December 31, 2008.

Because our marketing resources are limited, we may be unable to devote sufficient resources to SANCTURA and VANTAS to maintain, or achieve increasing, market acceptance of SANCTURA in the highly competitive marketplace for overactive bladder therapies and VANTAS in the highly competitive market for prostate cancer treatments. Our failure to

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expend the resources to adequately promote SANCTURA and VANTAS would have a material adverse effect on our business and results of operations. In addition, if successfully approved by the FDA, we expect to launch additional products for sale in 2007 and in the future, but there can be no assurance that such products will achieve market acceptance.

Moreover, because we have fewer sales representatives than our competitors, our sales force may be unable to market successfully to physicians who prescribe overactive bladder medications and prostate cancer treatments. We may not be able to retain all of our current sales representatives. Even if we hire additional representatives, they may not be effective in promoting the sale of SANCTURA and VANTAS. The failure of our sales representatives to be successful in selling SANCTURA and VANTAS would have a material adverse effect on operating results.

***We may not compete successfully in the overactive bladder market.***

Since the launch of SANCTURA in August 2004, two other competitive products were launched in early 2005 in the overactive bladder market. These launches increased the already intense competition in the overactive bladder market. SANCTURA may not compete successfully with current drug therapies or with new drugs which may reach the market in the future. SANCTURA competes with drugs and other therapies for overactive bladder marketed by many large, multinational companies who have substantially greater marketing and financial resources and experience than Indevus. In addition, antimuscarinics and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including certain treatments for which approval may be sought 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.

Our license for SANCTURA does not include any patents that we expect to use in commercializing the product for overactive bladder. 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 trosipium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly. We cannot predict whether any patents will issue on the applications that have been filed for SANCTURA XR, an extended release, once-daily formulation of SANCTURA. 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.

***Our product candidates, SANCTURA XR, VALSTAR, and NEBIDO, may not be successfully developed or achieve market acceptance.***

We currently have ten compounds or products which are in various stages of development and have not been approved by the FDA, including SANCTURA XR, VALSTAR, and NEBIDO. 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 are unable to predict whether any of these product candidates will receive regulatory clearances or will be successfully manufactured or marketed. Further, 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, our products may not achieve or maintain market acceptance.

***We rely on the favorable outcome of clinical trials of our product candidates including SANCTURA XR, VALSTAR, and NEBIDO.***

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. 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



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significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. For example, while there have been three Phase II clinical trials of paxlovid that demonstrated statistically significant efficacy, two in panic disorder and one in generalized anxiety disorder, or GAD, other trials have failed to demonstrate statistically significant efficacy, prompting 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 paxlovid.

### *We have regulatory and guideline risks.*

In May 2004, the FDA approved SANCTURA, in October 2004 the FDA approved VANTAS and in April 2007 the FDA approved SUPPRELIN LA. The FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse effect 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.

If SANCTURA, VANTAS or SUPPRELIN LA 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 SANCTURA or VANTAS are sold.

Government agencies promulgate regulations and guidelines directly applicable to us and SANCTURA and VANTAS. 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 SANCTURA or VANTAS or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of SANCTURA or VANTAS.

Acceptable levels of reimbursement for costs of developing and manufacturing of pharmaceutical products and treatments related to those pharmaceutical products by government authorities, private health insurers and other organizations, such as HMOs, will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, our products and product candidates. 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. 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 may not be able to obtain a satisfactory financial return on our own manufacturing and commercialization of any future products.

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.

**Table of Contents*****We are dependent on third parties to manufacture SANCTURA and SANCTURA XR.***

We are currently dependent on Madaus GmbH to manufacture SANCTURA and will be dependent on a third party for the manufacture of 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 the other 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 or SANCTURA XR.

***We are dependent on single suppliers for certain services and raw materials, including histrelin, that are necessary for the manufacture of our Hydron implants. If any of these suppliers fail or are unable to perform in a timely and satisfactory manner, we may be unable to manufacture VANTAS, SUPPRELIN LA or some of our product candidates, which could delay sales of VANTAS and SUPPRELIN LA and hinder research and development of our product candidates that use Hydron Technology.***

We currently rely on single suppliers for histrelin, the active ingredient in VANTAS and SUPPRELIN LA, for our implantation devices and for sterilization services for our implants, including VANTAS and SUPPRELIN LA. We do not currently have any written agreements with any of these suppliers. Although we have identified alternate sources of these raw materials and services, these raw materials and services may not be immediately available to us. Further, even if these alternative raw materials are immediately available, they must first meet our internal specifications. 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 VANTAS and SUPPRELIN LA or our product candidates in a timely manner or at all, which could delay the production or sale of VANTAS and SUPPRELIN LA and hinder the research and development of some of our product candidates. Our inability to obtain these raw materials and services for the manufacture of our implants may force us to cease or reduce operations.

***Prior to the merger with Indevus, Valera had previously experienced disruptions in its manufacturing of VANTAS due to issues caused by its supply of histrelin, the active ingredient in VANTAS and SUPPRELIN LA, including a manufacturing disruption during the second and third quarters of 2005 that caused a material decrease in its sales for the third quarter of 2005 and which may have an adverse impact on sales of VANTAS in the future. Further interruptions in the manufacturing process for VANTAS and SUPPRELIN LA or other product candidates may have an adverse impact on sales of VANTAS and SUPPRELIN LA and the development of other product candidates in the future.***

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, the active ingredient in VANTAS and SUPPRELIN LA. In the fourth quarter of 2004, Valera experienced difficulties processing histrelin in its raw, powder form. These difficulties delayed the manufacturing of VANTAS for several weeks as its supplier reformulated the histrelin. In the second and third quarters of 2005, Valera experienced an issue with the histrelin used to produce five lots of VANTAS. This issue, which was caused by the method by which its supplier formulated the histrelin, ultimately resulted in these five lots not meeting certain quality control specifications and caused a delay in production of approximately six weeks. Valera resolved each of these issues and developed additional specifications with its supplier of histrelin in an effort to ensure a more consistent supply of histrelin that meets its needs. However, the disruption Valera experienced in the second and third quarters of 2005 directly impacted its supply of VANTAS in the third quarter of 2005 by limiting the amount of finished product available for sale in the quarter to three lots, or approximately 2,400 units. Its third quarter sales were 1,747 units, which was less than its sales in the first and second quarters of 2005, in which Valera sold 2,925 units and 3,974 units, respectively. As a result of this decrease in sales, Valera had a net loss in the third quarter of 2005.

The interruption in its supply of VANTAS in the second and third quarters of 2005 may have an adverse effect on our ability to sell VANTAS in the future. The lack of supply during that period 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. Additionally, in the future, we may experience other disruptions in its manufacturing process for VANTAS and SUPPRELIN LA or our product candidates. Any disruptions we may experience may adversely impact sales of VANTAS and SUPPRELIN LA or the development of our product candidates.

***The successful commercialization of VANTAS and any other products we develop will depend on obtaining reimbursement at adequate levels from private health insurers and Medicare/Medicaid for patient use of these products. We expect the reimbursement levels for VANTAS to decline, which will have an adverse effect on our net product sales.***

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



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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 VANTAS and other products we may develop could affect the extent to which we are able to commercialize these products.

VANTAS is currently eligible for insurance reimbursement coverage. Sales of VANTAS in the first half of 2005 were supported, in part, by favorable reimbursement rates, which decreased at the beginning of the third quarter of 2005. The favorable reimbursement rates Valera experienced in the first half of 2005 were due to the fact that VANTAS was a new product that did not yet have an established average selling price, or ASP. As a result, VANTAS was reimbursed at wholesale acquisition price, which is typically higher than ASP. VANTAS received an established ASP effective July 2005, which has resulted in declining reimbursement rates for VANTAS.

We expect future Medicare reimbursement levels to continue to decline for VANTAS, which will have an adverse effect on our net product sales. Reimbursement levels are currently set by the twenty three 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 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 VANTAS or any other products that we may develop and reimbursement or coverage levels may reduce the demand for, or the price of, VANTAS or any other products that we may develop. If we cannot maintain coverage for VANTAS and obtain adequate reimbursement for other products we develop, the market for those products may be limited.

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 VANTAS 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 VANTAS 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 VANTAS and other products we may develop in commercially acceptable quantities at profitable prices may be harmed.

***As a manufacturer of some of our products, we will be subject to regulatory requirements. If we do not comply with such requirements, the development and sales of our products and our financial performance may be materially harmed. Further, we rely on third parties to manufacture many of our products.***

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 SANCTURA, 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. 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.

Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with current good manufacturing practices, or cGMP, requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are 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. 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. Currently, Schering's NEBIDO manufacturing facilities have not been approved by the FDA.

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.

***We may not be able to manufacture the VALSTAR (valrubicin) product or realize a return on our investment in this product candidate.***

In March 2006, Valera acquired certain assets associated with its valrubicin product for the treatment of bladder cancer from Anthra Pharmaceuticals, Inc., including the right to sell the product in the United States and Canada. This product was withdrawn from the market in 2002 due to a manufacturing problem. We may not realize a return on this investment in such assets due to risks related to the lack of intellectual property protection and potential manufacturing difficulties. Even if the FDA agrees to the reintroduction plan, there is no assurance that we will be able to successfully implement the plan. Further, we will not have exclusive rights with respect to the sale of the valrubicin product, because the product 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.

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Although we believe that we have identified the cause of the previous manufacturing problem and that it will be corrected, there can be no assurance that the problem will be corrected or that there will not be manufacturing problems in the future. Even if we establish an acceptable manufacturing protocol, our third-party manufacturers may be unable to manufacture the product in sufficient quantities with the correct specifications or in compliance with cGMP or other applicable regulatory requirements. As a result of these risks, we may be unable to realize a return on our investment in this product.

### ***We rely on third parties to commercialize our products.***

We have limited sales and marketing capabilities to market our products. Substantial additional funds will be required to complete development and commercialization of our product candidates and, accordingly, 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 or our security holders. 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.

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 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.

### ***Our failure to acquire and develop additional product candidates will impair our ability to grow.***

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 may undertake additional 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, including with respect to the merger with Valera. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than Indevus predicts. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions Indevus may consummate could result in the disruption of our on-going business or inconsistencies in standards, controls, procedures and policies that could negatively affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. Moreover, we may need to raise additional funds through public or private debt or equity financing 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 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.

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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 need additional funds in the near future.***

Our existing cash resources will be insufficient to commercialize any of our current product candidates on our own. 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 2007 as we continue to fund our development activities, as well as marketing activities related to SANCTURA, VANTAS, DELATESTRYL and SUPPRELIN LA. We may seek 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 a strategic 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 depressive 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.

Our cash requirements and cash resources will vary significantly depending upon the following principal factors:

marketing success of SANCTURA and VANTAS;

approval of SANCTURA XR and the payment of the related milestone to us by Esprit;

marketing success of DELATESTRYL, sales of which may be negatively impacted if NEBIDO, another treatment for male hypogonadism, is introduced to the market;

the costs and progress of our research and development programs;

the timing and cost of obtaining regulatory approvals; and

whether we are successful in either in-licensing or out-licensing products.

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 \$17,600,000, \$31,800,000, \$68,200,000, \$53,200,000 and \$50,600,000 for fiscal years 2002, 2003, 2004, 2005, and 2006, respectively. At March 31, 2007 we had an accumulated deficit of approximately \$495,400,000.

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

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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.***

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.

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***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 AHP, 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 rely on the protection provided by our intellectual property and have limited patent protection on some of our products.***

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

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. 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.

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.

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Our license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents that we expect to use in the commercialization of the product for overactive bladder. We do not otherwise currently own or have a license to issued patents that cover our SANCTURA product.

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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.

### ***We may depend on market exclusivity for certain of our products.***

Assuming regulatory approvals are obtained, our ability to commercialize successfully certain drugs may depend on the availability of market exclusivity or patent extension under the Waxman-Hatch Act, which provides protections for certain new 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. We are relying on market exclusivity under the Waxman-Hatch Act for SANCTURA.

### ***Our products may be unable to compete successfully with other products.***

Competition from other pharmaceutical companies is intense and is expected to increase. We are aware of existing products and of products under development by our competitors that address diseases we are targeting and competitors have developed or are developing products or technologies that are, or may compete with our products.

Many of the other 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. As a result, our



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products may not be able to compete successfully. In addition, royalties payable to us under certain conditions may be reduced or eliminated if there is generic competition. 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.

We compete against all pharmaceutical companies that manufacture or market LHRH agonist products. We also compete against biotechnology companies, universities, government agencies, and other research institutions in the development of urological and endocrine products, technologies and processes that are, or in the future may be, the basis for competitive commercial products.

In particular, we will compete against the following LHRH agonist products for the palliative treatment of advanced prostate cancer: TAP Pharmaceutical Products Lupron and Sanofi-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 Bayer Pharmaceuticals Viadur, a rigid metal implant that releases leuprolide over a 12-month period. With respect to the endocrine pharmaceuticals in late-stage development for the treatment of central precocious puberty and acromegaly, current competitors include TAP Pharmaceutical Products Lupron Depot-PED, Novartis Sandostatin injections and Sandostatin LAR Depots and Pfizer's Somavert.

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

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept or utilize the associated products. 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.

***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 intend to market our products outside of the U.S. For example, we have assumed Valera's agreements to license VANTAS in Europe, 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. 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.

***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, 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. We will conduct certain clinical trials for the octreotide implant in Europe; however, we have employed a local contract research organization to monitor the trials. We will also contract with a third party to handle the data management for these trials.

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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 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 Madaus or Esprit, related to SANCTURA and SANCTURA XR, our agreement with Aventis, under which we license pagoclone, or our agreements with Schering, under which we license NEBIDO, could substantially reduce the likelihood of successful commercialization of our product candidates which would materially harm us. The agreements with Esprit, Madaus, Aventis or Schering 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.

***Our sales of SANCTURA, VANTAS and any other products we may develop could suffer from competition by generic products.***

Although we will have proprietary protection for VANTAS and other products we are developing, we could face competition from generic substitutes of these products as well as SANCTURA if generics are developed by other companies and approved by the FDA. 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. Competition from the sale of generic 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.

***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, Bobby W. Sandage, Jr., our Chief Scientific Officer, and John H. Tucker, our Chief Sales and Marketing 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 among pharmaceutical and biotechnology companies is intense, and the loss of any qualified employees, or an inability to attract, retain and motivate highly skilled employees, could adversely affect our business and prospects. Competition to attract and retain pharmaceutical sales people is intense. We may not be able to attract additional qualified employees or retain our existing personnel.

***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, including SUPPRELIN LA, SANCTURA XR, VALSTAR and NEBIDO. 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

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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.

### **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 are currently issued and outstanding. 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.

*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;

ability to successfully commercialize SUPPRELIN LA;

results of clinical studies and regulatory reviews;

the marketing approval of SANCTURA XR;

approval of SANCTURA XR and the payment of the related milestone to us by Esprit;

results of our NEBIDO Phase III pharmacokinetic study;

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, and stock issued upon conversion of the contingent stock rights, issued in connection with the merger;

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 competitors, 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 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, \$6.62 and \$2.52 for fiscal 2006 and \$7.96 and \$5.67 for the six month period ended March 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.

***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. 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 issues our shares subject to options, warrants, convertible notes, stock awards or other arrangements.***

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

10,817,308 shares issuable upon conversion of the \$72,000,000 Convertible Senior Notes issued in July 2003, which are due in July 2008;

12,814,988 shares issuable upon exercise of outstanding options and Performance Stock Awards, 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;

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

4,610,324 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.

We are obliged to issue shares of common stock upon achievement of development milestones related to CSRs issued in connection with the acquisition of Valera. As of May 3, 2007, as a result of the FDA approval of SUPPRELIN LA and our possession of a specified amount of inventory of commercially sellable units, approximately 2,300,000 shares are issuable. The achievement of future milestones related to two other outstanding CSRs could result in the issuance of shares, the amount of which is dependent upon the price of Indevus common stock at the time of achievement.

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### ***Increased leverage as a result of our convertible debt offering may harm our financial condition and results of operations.***

At March 31, 2007, we had \$72,000,000 of outstanding debt reflected on our balance sheet relating to our outstanding Convertible Notes. If the price of our common stock at the time the convertible debt is due does not exceed 150% of the conversion price then in effect for a specified period, then we may not be able to redeem the notes to cause a conversion, and then we may be obligated to repay the note holders in cash on the July 2008 due date. We may incur additional indebtedness in the future and the Convertible 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 Convertible Notes;

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.

## **Item 6. Exhibits**

### (a) Exhibits

3.1 Certificate of Amendment of Restated Certificate of Incorporation, as amended (1)

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 (1)



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- 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 (1)
- 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 (1)
- 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 (1)

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(1) Filed with this report.

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**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC.

Date: May 10, 2007

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

INDEVUS PHARMACEUTICALS, INC.

Date: May 10, 2007

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

INDEVUS PHARMACEUTICALS, INC.

Date: May 10, 2007

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