INDEVUS PHARMACEUTICALS INC
Form 10-Q
August 08, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2008

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

Commission File No. 0-18728

INDEVUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3047911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

33 Hayden Avenue

Lexington, Massachusetts	**02421-7971**
(Address of principal executive offices)	**(Zip Code)**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

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

Class:	**Outstanding at August 4, 2008**
Common Stock $.001 par value	**77,553,315 shares**

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(Amounts in thousands except share data)

	June 30, 2008	September 30, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,624	$ 71,142
Accounts receivable, net	10,834	7,249
Inventories	10,064	7,729
Prepaid and other current assets	5,770	4,708
Total current assets	79,292	90,828
Property, plant and equipment, net	9,827	9,771
Inventories	620	682
Goodwill	48,244	48,244
Intangible assets, net	31,492	29,190
Other assets	4,283	4,335
Total assets	$ 173,758	$ 183,050
LIABILITIES		
Current liabilities:		
Accounts payable	$ 6,855	$ 4,505
Accrued expenses	20,455	24,704
Accrued interest	2,075	950
Deferred revenue	43,424	21,946
6.25% Convertible notes	75	75
Total current liabilities	72,884	52,180
6.25% Convertible notes	69,638	68,037
Deferred revenue, net of current portion	146,353	136,515
Other	2,946	656
STOCKHOLDERS DEFICIT		
Convertible Preferred Stock, $.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding as of September 30, 2007 (liquidation preference at September 30, 2007 of $3,026)		3,000
Series C, 5,000 shares issued and outstanding as of September 30, 2007 (liquidation preference at September 30, 2007 of $502)		500
Common Stock, $.001 par value, 200,000,000 shares authorized; 77,553,315 and 76,360,039 shares issued and outstanding at June 30, 2008 and September 30, 2007, respectively	78	76
Additional paid-in capital	509,934	498,587
Accumulated deficit	(628,075)	(576,501)
Total stockholders deficit	(118,063)	(74,338)

Total liabilities and stockholders deficit	$ 173,758	$ 183,050

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

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INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For the three and nine months ended June 30, 2008 and 2007

(Unaudited)

(Amounts in thousands except per share data)

	Three months ended June 30,		Nine months ended June 30,	
	2008	2007	2008	2007
Revenues:				
Product revenue	$ 8,221	$ 6,406	$ 22,727	$ 15,118
Contract and license fees	12,198	5,819	31,734	21,482
Total revenues	20,419	12,225	54,461	36,600
Costs and expenses:				
Cost of revenues	7,837	3,483	20,104	9,033
Research and development	5,222	10,303	17,867	29,494
Marketing, general and administrative	20,657	19,755	59,699	41,445
Acquired in-process research and development		50,000		50,000
Amortization of intangible assets	637	414	1,630	414
Restructuring	3,529		3,529	
Total costs and expenses	37,882	83,955	102,829	130,386
Loss from operations	(17,463)	(71,730)	(48,368)	(93,786)
Investment income	390	688	2,159	2,591
Interest expense	(1,891)	(1,293)	(5,364)	(3,878)
Net loss	$ (18,964)	$ (72,335)	$ (51,573)	$ (95,073)
Net loss per common share, basic and diluted	$ (0.25)	$ (1.02)	$ (0.67)	$ (1.56)
Weighted average common shares outstanding, basic and diluted	77,071	70,922	76,515	60,897

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 nine months ended June 30, 2008 and 2007

(Unaudited)

(Amounts in thousands)

	For the nine months ended June 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	$ (51,573)	$ (95,073)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	3,327	915
Note discount amortization	1,840	508
Noncash stock-based compensation	5,316	5,913
Loss on disposal of property, plant and equipment	1,068	
Lease abandonment	353	
Inventory impairment	500	1,100
Acquired in-process research and development		50,000
Noncash exchange of asset		1,100
Changes in assets and liabilities, net of assets and liabilities acquired:		
Accounts receivable	(3,585)	(2,239)
Inventories	(2,773)	106
Prepaid and other assets	(1,293)	(759)
Accounts payable	2,350	(788)
Accrued expenses and other liabilities	(4,083)	3,310
Deferred revenue	31,316	(1,836)
Net cash (used in) operating activities	(17,237)	(37,743)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(2,822)	(477)
Purchase of intangible asset	(1,000)	
Proceeds from maturities and sales of marketable securities		5,956
Cash acquired, net of business acquisition costs		3,130
Net cash (used in) provided by investing activities	(3,822)	8,609
Cash flows from financing activities:		
Net proceeds from issuance of common stock	2,541	1,042
Net cash provided by financing activities	2,541	1,042
Net change in cash and cash equivalents	(18,518)	(28,092)
Cash and cash equivalents at beginning of period	71,142	70,169
Cash and cash equivalents at end of period	$ 52,624	$ 42,077

Supplemental disclosures of cash flow information and noncash transactions:		
Payable to Shire for manufacturing and supply agreement termination (see Note H)	$ 3,062	$
Issuance of common stock related to acquisition (see Note C)	$	$ 137,275

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

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INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

The consolidated interim financial statements included herein have been prepared by Indevus Pharmaceuticals, Inc. (Indevus or the Company) without audit, pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company. The unaudited consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company s Form 10-K for the fiscal year ended September 30, 2007.

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

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

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

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

On June 27, 2008, the Company announced the receipt of an approvable letter from the U.S. Food and Drug Administration (FDA) for NEBIDO related to a New Drug Application (NDA) submitted to the FDA in August 2007. The letter indicated that the application may be approved if the Company is able to adequately respond to certain clinical deficiencies related to the product.

The FDA has requested the Company address these clinical deficiencies by providing detailed safety information from clinical studies to determine the precise incidence of serious post-injection oil-based reactions and allergic reactions. Specifically, the FDA has requested follow-up data from the on-going U.S. and European studies in which patients are being treated with NEBIDO on an extended basis. A majority of these trials are scheduled to be completed within twelve months. The FDA stated that depending on the findings, the number of subjects and the number of injections of testosterone undecanoate, the safety database may need to include data from additional clinical studies. They have requested that the Company propose the size of the safety database (i.e. total number of subjects exposed to testosterone undecanoate intramuscular injection and total number of injections) and the rationale for the size of the proposed safety database Additionally, the FDA has requested the Company to provide a plan to minimize the risks associated with the clinical use of testosterone undecanoate intramuscular injection.

The Company will work with the FDA and its partner, Bayer Schering Pharma AG, to respond to the approvable letter and devise a plan to address the deficiencies. While the FDA has not specifically requested additional clinical studies, the Company believes that an additional study will likely be required to demonstrate that NEBIDO 750 mg (3 cc volume) administered with careful and proper intramuscular injection technique, has an acceptably low incidence of oil-based reactions to gain approval. The Company hopes to be able to articulate a development plan to address FDA concerns within the next few months. The Company estimates that it could take approximately 18 months to re-submit the revised NDA.

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B. Accounting Policies

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

Royalty revenue consists of payments received from licensees for a portion of the sales proceeds from products that utilize the Company s licensed technologies. Royalties are generally reported to the Company in a royalty report on a specified periodic basis and recognized in the period in which the sales of the product or technology on which the royalties are based occurred. If the royalty report for such period is received subsequent to the time when the Company is required to report its results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of, and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments, and since October 2007, sales of SANCTURA and SANCTURA XR product. The Company s business strategy includes entering into collaborative license, development, supply and co-promotion agreements with strategic partners for the development and commercialization of the Company s products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments resulting from the achievement of certain milestones and royalties on net product sales.

Many of the Company s agreements contain multiple elements and require evaluation pursuant to Emerging Issues Task Force (EITF) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). Pursuant to EITF 00-21, in multiple element arrangements where the Company has continuing performance obligations, contract, milestone and license fees are recognized together with any up-front payments over the term of the arrangement as the Company completes its performance obligations, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered elements in the arrangement. In the case of an arrangement where it is determined that there is a single unit of accounting, all cash flows from the arrangement are aggregated and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. The Company records such revenue as contract and license fee revenue.

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

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

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

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

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

Accounting for Stock-Based Compensation: The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted SFAS 123R, *Accounting for Stock-Based Compensation* (SFAS 123R). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. The Company is required to make significant estimates related to SFAS 123R. The Company s expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended June 30, 2008 and 2007, the Company used a weighted-average expected stock-price volatility of 49.0% and 51.9%, respectively. For stock option grants issued to non-executives during the nine months ended June 30, 2008 and 2007, the Company used a weighted-average expected stock-price volatility of 49.0% and 53.8%, respectively. The Company did not issue any stock option grants to executives during the three months ended June 30, 2008 and 2007. In addition, the Company did not issue any stock option grants to executives during the nine months ended June 30, 2008. For stock option grants issued to executives during the nine months ended June 30, 2007, the Company used a weighted average expected stock-price volatility of 62.8%. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. The Company also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended June 30, 2008 and 2007, the Company used a weighted-average expected option life assumption of 6.0 and 6.57 years, respectively, for non-executives. For stock option grants made during the nine months ended June 30, 2008 and 2007, the Company used a weighted-average expected option life assumption of 6.25 and 6.53 years, respectively, for non-executives. For stock option grants made during the nine months ended June 30, 2007, the Company used a weighted-average expected option life assumption of 8.0 years for executives.

During the three months ended June 30, 2008, the Board of Directors approved modifications to extend the term of certain outstanding fully vested options and the Company recorded $560,000 of noncash compensation expense related to these modifications. Pursuant to FAS123R, the Company is required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of stock options.

The Company has also granted restricted stock units and performance stock awards. The value of these awards is being expensed over the respective vesting period. For the three months ended June 30, 2008 and 2007, the Company recognized $348,000 and $245,000, respectively, in stock-based compensation. For the nine months ended June 30, 2008 and 2007, the Company recognized $1,000,000 and $725,000, respectively, in stock-based compensation.

Inclusive of the above stock-based compensation, during the three months ended June 30, 2008 and 2007, the Company recognized $2,040,000 and $3,267,000, respectively, in total stock-based compensation. During the nine months ended June 30, 2008 and 2007, the Company recognized $5,316,000 and $5,913,000, respectively, in total stock-based compensation.

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

C. Valera Acquisition

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

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

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

The following represents the unaudited pro forma results of the ongoing operations for Indevus and Valera as though the acquisition of Valera had occurred at the beginning of the three and nine month periods ended June 30, 2007. The unaudited pro forma information, however, is not necessarily indicative of the results that would have resulted had the acquisition occurred at the beginning of the periods presented, nor is it necessarily indicative of future results.

	Three months ended June 30, 2007 (Pro forma)	Nine months ended June 30, 2007 (Pro forma)
Revenue	$ 12,894,000	$ 43,708,000
Net loss	$ (79,795,000)	$ (114,470,000)
Net loss per common share (basic and diluted)	$ (1.05)	$ (1.52)

D. Goodwill and Intangible Assets

The carrying amount of goodwill is $48,244,000 at June 30, 2008 and was recorded in connection with the Valera Acquisition and the subsequent conversion of CSRs and CSR Equivalents issued to the former shareholders of Valera relating to FDA approval of SUPPRELIN LA on May 3, 2007.

The Company s intangible asset totaled approximately $31,492,000 as of June 30, 2008. Approximately $27,700,000 of the Company s net intangible assets were obtained as a result of the Valera Acquisition. In April 2008, the Company entered into an agreement to terminate its existing manufacturing and supply agreement with Shire plc (Shire). In exchange for upfront and installment payments aggregating $5,000,000, the Company is no longer obligated to pay future royalties to Shire. The Company capitalized the worldwide, exclusive license to VANTAS upon termination of the agreement which resulted in an additional intangible asset of approximately $3,792,000 as of June 30, 2008 (see Note H). Amortization of this intangible asset is being recognized on a straight line basis over the remaining term of the license agreement, which is approximately 6.5 years.

Amortization expense for intangible assets totaled approximately $637,000 and $414,000 for the three months ended June 30, 2008 and 2007, respectively, and approximately $1,630,000 and $414,000 for the nine months ended June 30, 2008 and 2007, respectively.

The annual amortization expense for each of the next five years is expected to be approximately $2,500,000.

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E. Inventories

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

	June 30, 2008	September 30, 2007
Raw materials	$ 5,518,000	$ 771,000
Work in process	3,012,000	4,405,000
Finished goods	2,154,000	3,235,000
	$ 10,684,000	$ 8,411,000

All of the Company s inventories at the balance sheet date relate to commercially approved products: SANCTURA XR, VANTAS, SUPPRELIN LA and DELATESTRYL. The Company has classified $620,000 and $682,000 of DELATESTRYL inventory as noncurrent as of June 30, 2008 and September 30, 2007, respectively.

F. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	Useful Lives	June 30, 2008	September 30, 2007
Manufacturing and office equipment	2 - 7 years	$ 6,417,000	$ 4,373,000
Leasehold improvements	5 -10 years	6,814,000	6,309,000
Construction in progress		182,000	1,011,000
		13,413,000	11,693,000
Less: accumulated depreciation and amortization		(3,586,000)	(1,922,000)
Property, plant and equipment, net		$ 9,827,000	$ 9,771,000

Depreciation and amortization expense for property, plant and equipment was approximately $687,000 and $372,000 for the three months ended June 30, 2008 and 2007, respectively and approximately $1,697,000 and $502,000 for the nine months ended June 30, 2008 and 2007, respectively.

G. Basic and Diluted Loss per Common Share

During the three month period ended June 30, 2008, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 9,115,000 shares of Common Stock at prices ranging from $3.80 to $8.72 with various expiration dates up to June 3, 2018. Additionally, during the three month period ended June 30, 2008, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect, were as follows: (i) $71,925,000 of 6.25% Convertible Senior Notes due in 2009 and $75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes) which are convertible into a total of 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes due in 2008 and through July 15, 2009 with respect to the Convertible Notes due in 2009; (ii) options to purchase 4,805,000 shares of Common Stock at prices ranging from $1.22 to $3.70 with various expiration dates up to October 17, 2015; (iii) unvested restricted stock with service-based vesting criteria of 209,001 shares and unvested restricted stock awards with service and market-based vesting criteria of 330,560 to 566,300 contingently issuable shares; and (iv) unvested deferred stock units with service vesting criteria of 86,667 shares of Common Stock.

During the three month period ended June 30, 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 were convertible through July 15, 2008 because the effect of their conversion would have been antidilutive; (ii) options to purchase 560,000 shares of

Common Stock at prices ranging from $7.21 to $8.72 with expiration dates ranging up to June 5, 2017 because their exercise price exceeded the average market price during the period; and (iii) contingent stock rights of 487,707 at a price of $7.34 because the effect of their conversion would have been antidilutive. Additionally, during the three month period ended June 30, 2007, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have had an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 12,562,000 shares of Common Stock at prices ranging from $1.22 to $7.14 with expiration dates ranging up to April 23, 2017; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (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; and (iv) unvested deferred stock units with service vesting criteria of 48,000 shares of Common Stock.

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During the nine month period ended June 30, 2008, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 6,842,000 shares of Common Stock at prices ranging from $5.63 to $8.72 with various expiration dates up to February 5, 2018. Additionally, during the nine month period ended June 30, 2008, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect, were as follows: (i) $71,925,000 of 6.25% Convertible Senior Notes due in 2009 and $75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes), which are convertible into a total of 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes due in 2008 and through July 15, 2009 with respect to the Convertible Notes due in 2009; (ii) options to purchase 13,985,000 shares of Common Stock at prices ranging from $1.22 to $5.53 with various expiration dates up to May 6, 2018 (iii) unvested restricted stock with service-based vesting criteria of 209,001 shares and unvested restricted stock awards with service and market-based vesting criteria of 330,560 to 566,300 contingently issuable shares; and (iv) unvested deferred stock units with service vesting criteria of 86,667 shares of Common Stock.

During the nine month period ended June 30, 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 were convertible through July 15, 2008 because the effect of their conversion would have been antidilutive ; (ii) options to purchase 958,000 shares of Common Stock at prices ranging from $6.98 to $8.72 with expiration dates ranging up to June 5, 2017 because their exercise price exceeded the average market price during the period; and (iii) contingent stock rights of 487,707 at a price of $7.34 because the effect of their conversion would have been antidilutive. Additionally, during the nine month period ended June 30, 2007, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have had an antidilutive effect due to the net loss for the period were as follows: (i) options to purchase 11,604,000 shares of Common Stock at prices ranging from $1.22 to $6.93 with expiration dates ranging up to March 19, 2017; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (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; and (iv) unvested deferred stock units with service vesting criteria of 48,000 shares of Common Stock.

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

H. Agreements

Allergan/Esprit

In September 2007, the Company entered into the Allergan Agreement with Esprit Pharma, Inc. (Esprit), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR. The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, the Company received an up-front license fee, partially creditable by Allergan against future payments to the Company, of $25,000,000. The Allergan Agreement also grants the Company the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately $123,000,000 over the first seven years of the Agreement, provided there is no product adverse event, as defined in the Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, Allergan may reduce, subject to quarterly and annual restrictions, royalty payments by $20,000,000. In addition, the Company will receive approximately $9,000,000 in annual sales force subsidy for fiscal year 2008 which has been extended to December 31, 2008 and which can be extended to March 31, 2009 at the Company s option. Third-party royalties payable by the Company as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will also be reimbursed to the Company. The Company will also manufacture and supply SANCTURA XR through approximately August 2008, and SANCTURA through September 30, 2012, to Allergan at cost. The Company may also receive a long-term commercialization milestone payment of $20,000,000 related to generic competition. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR, which occurred in January 2008, or the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

Commencing on the effective date of the Allergan Agreement, the Company began recognizing the deferred revenue balances that existed on the effective date and the upfront license payment of $25,000,000 on a straight-line basis over the approximately 5 year obligation period of the agreement. All subsequent payments received from Allergan during the 5 year

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obligation period of the agreement, including royalties, sales force reimbursement and product revenues, will be recognized using the CAPM. All payments received after the 5 year obligation period of the agreement will be recognized as revenue when earned, provided that there are no remaining obligations.

In May 2008, together with Madaus, the Company also licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, the Company received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The performance period continues through September 30, 2012. All consideration received from Allergan during the term will be recognized using the CAPM over the performance period.

Collectively through June 30, 2008 and pursuant to all agreements between the Company and PLIVA d.d. (PLIVA), Esprit and Allergan, the Company has received approximately $351,000,000 in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to the Company s marketing partners at its cost to manufacture.

VANTAS

In April 2008, the Company entered into an agreement to terminate its manufacturing and supply agreement with Shire plc (Shire) related to VANTAS. Under this termination agreement, Shire relinquished its right to receive royalties on net sales of VANTAS or a percentage of royalties and other consideration received by the Company relative to a sublicense of our VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for the Company to pay Shire a total of $5,000,000 consisting of an immediate payment of $1,000,000 and the balance of $4,000,000 in three annual installments commencing in January 2009. The Company capitalized the net present value of the total $5,000,000 payment using a discount rate of 17.5%, resulting in a $3,900,000 intangible asset. Amortization of the intangible asset is being recognized over the remaining term of the license agreement, which is approximately 6.5 years. After consideration of the $1,000,000 payment, there is approximately $1,000,000 classified as a short-term obligation and $2,100,000 classified as a long-term obligation in the consolidated June 30, 2008 balance sheet. This remaining obligation will be accreted up to its face value over the payment term through charges to interest expense.

In April 2008, the Company entered into a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries. VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark and the United Kingdom. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. The Company received a $7,000,000 up-front payment and could receive certain contingent payments related to approvals and sales thresholds aggregating up to $14,000,000. Additionally, the Company has agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. The agreement expires in April 2023, subject to earlier termination by either party under certain customary conditions of breach. The Agreement will automatically renew for one-year periods at a time, subject to the right of either party to terminate the agreement at any time effective at the end of the initial 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party. Commencing on the first sale of product to Orion, the Company will recognize the $7,000,000 up-front payment as revenue over the 15-year term of the agreement in accordance with the proportional performance method using the minimum supply quantities to estimate completion of the earnings process. Expected performance will be assessed quarterly to incorporate changes in estimates and milestone payments received.

IP 751

In October 2007, the Company licensed its worldwide rights to IP 751 to Cervelo and received an upfront payment of $1,000,000. In the three month period ended June 30, 2008, the Company recognized this payment as contract and license fee revenue upon completion of its obligations to Cervelo. In addition, the Company could receive further payments based on regulatory and, if approved for marketing, commercial achievements aggregating approximately $37,000,000, and royalties based upon net sales. Cervelo is responsible for all future development, manufacturing, marketing and financial obligations relating to IP 751. This agreement will terminate ten years after first commercial sale on a country-by-country basis and may be terminated by either party under certain customary conditions of breach and by Cervelo upon six months notice to the Company.

PRO 2000

In February 2008, the Company was advised by the United Kingdom s Medical Research Council (MRC) that after review of data from the Phase III clinical trial of PRO 2000, its candidate vaginal microbicide for HIV prevention, the

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

ALKS

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

VALSTAR

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

In August 2007 the Company received an approvable letter from the FDA for VALSTAR asking for clarification regarding manufacturing validation protocols and additional data on the manufacturing process which was promptly provided. In December 2007, based on the FDA s subsequent inspection of our third-party manufacturing facility, the Company received a non-approvable letter from the FDA. The Company is working with the FDA and their third-party manufacturer to bring the manufacturing facility into compliance with U.S. current Good Manufacturing Practices (cGMP). The Company anticipates resolving these issues by October 2008.

PLANTEX

The Company has a supply agreement with Plantex USA Inc. whereby Plantex will supply the Company with Valrubicin, the active pharmaceutical ingredient for VALSTAR. The Agreement will expire ten years after the date of the first commercial sale of VALSTAR provided VALSTAR is approved by December 31, 2008. Beginning in the calendar year following the year in which it receives regulatory approval for VALSTAR in the United States, the Company will have annual minimum purchase requirements of $1,000,000. This agreement may be terminated by either party under certain customary conditions of breach, by mutual agreement of the parties, or by Plantex if VALSTAR is not approved by December 31, 2008.

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

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

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date of the AHP Indemnity and Release Agreement, the Company s defense costs were paid by, or subject to reimbursement to the Company from, the Company s product liability insurers. To date, there have been no Redux-related product liability settlements or judgments paid by the Company or its insurers. In exchange for the indemnification, defense costs, and insurance coverage provided to Indevus by Wyeth, the Company agreed to dismiss its suit against Wyeth filed in January 2000, its appeal from the order approving Wyeth s national class action settlement of diet drug claims, and its cross-claims against Wyeth related to Redux product liability legal actions.

At June 30, 2008, the Company has an accrued liability of approximately $500,000 for Redux-related expenses, including legal expenses. The amount the Company ultimately pays could differ significantly from the amount currently accrued at June 30, 2008. To the extent the amount paid differs from the amount accrued, the Company will record a charge or credit to the statement of operations.

As of June 30, 2008, the Company had an outstanding insurance claim of approximately $3,300,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company s current outstanding insurance claim is made pursuant to the Company s product liability policy issued to the Company by Reliance Insurance Company (Reliance). In March 2008, the Company received a partial payment of $400,000 from Reliance pertaining to this claim. In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $858,000 reflecting the Company s best estimate given the available facts and circumstances. The amount the Company collects could differ from the $858,000 reflected as a noncurrent insurance claim receivable at June 30, 2008. It is uncertain when, if ever, the Company will collect any of its $3,300,000 of estimated remaining claims. If the Company incurs additional product liability defense and other costs subject to claims on the Reliance product liability policy up to the $5,000,000 limit of the policy, the Company will have to pay such costs without expectation of reimbursement and will incur charges to operations for all or a portion of such payments.

J. Stockholders Equity

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

K. Other

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

	June 30, 2008	September 30, 2007
Compensation related	$ 8,351,000	$ 5,351,000
Clinical and sponsored research	2,594,000	9,048,000
Sales and marketing	2,406,000	2,903,000
Professional fees	1,765,000	895,000
Manufacturing and production costs	847,000	2,243,000
Milestone payment		1,500,000
Other	4,492,000	2,764,000
	$ 20,455,000	$ 24,704,000

L. Restructuring

On June 30, 2008, the Company announced a restructuring of its operations to more appropriately align its cost structure to revenue projections and development opportunities. As a result of this restructuring, the Company recorded a restructuring charge of $3,500,000 during the three months ended June 30, 2008, relating to the following: (i) separation costs of approximately $2,300,000 and (ii) asset impairment charges of approximately $1,200,000 associated with the disposal of capital assets. The accrued restructuring balance was approximately $2,300,000 as of June 30, 2008, consisting primarily of unpaid separation costs, which are expected to be paid by June 30, 2009.

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

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M. Income Taxes

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

The Company adopted FIN 48 on October 1, 2007. The implementation of FIN 48 did not have a material impact on the Company s consolidated financial statements or results of operations. The Company does not have any unrecognized tax benefits. As of June 30, 2008, the Company had federal and state net operating loss carryforwards and federal and state research and development (R&D) credit carryforwards, which may be available to offset future federal and state income tax liabilities. The Company has not completed a formal R&D credit study, however, no amounts related to R&D credit carryforwards are being presented as an uncertain tax position under FIN 48.

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

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as a component of tax expense. This policy did not change as a result of the adoption of FIN 48. For the quarter ended June 30, 2008, the Company did not recognize any accrued interest and penalties in its consolidated statement of operations or its consolidated balance sheet.

N. Liquidity

The Company is subject to risks common to companies in the specialty pharmaceutical industry including, but not limited to, development by its competitors of new technological innovations, dependence on key personnel, its ability to protect proprietary technology, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA government regulations and approval requirements, its ability to grow its business and its ability to obtain adequate financing to fund its current and planned operations. The Company expects to continue to incur substantial expenditures for the development, commercialization and marketing of its products and product candidates. The Company believes its current and expected cash resources are sufficient to fund its operations through approximately June 2009. In addition, the Company s convertible notes of approximately $71,900,000 will become due in July 2009. The Company will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to the Company. The failure to raise such funds would result in the need to significantly curtail the Company s operating activities and delay development efforts, which would have a material adverse effect on the Company.

O. Recent Accounting Pronouncements

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

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

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

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

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

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

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

In April 2008, the FASB Staff Position (FSP) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP SFAS 142-3). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles (GAAP). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008 and will be adopted by the Company in the first quarter of fiscal year 2009. The Company is currently evaluating the effect that the adoption of FSP SFAS 142-3 will have on its results of operation and financial position or cash flows, but does not expect it to have a material impact.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU 411, *the Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS 162 to have a material effect on its results of operations and financial condition.

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In May 2008, the FASB issued FSP Accounting Principles Board (APB) 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP ABP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis and will be adopted by the Company in the first quarter of fiscal year 2009. The Company is currently evaluating the potential impact, if any, of the adoption of FSP APB 14-1 on its results of operations and financial condition.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward Looking Statements

Statements in this Form 10-Q that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets), SANCTURA XR (once-daily SANCTURA), NEBIDO®, (testosterone undecanoate), VANTAS® (histrelin implant for prostate cancer) and SUPPRELIN® LA (histrelin implant for central precocious puberty); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux -related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and trends and do not to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company s Form 10-K for the fiscal year ended September 30, 2007. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR, NEBIDO, VANTAS and SUPPRELIN LA; need for additional funds and corporate partners, including for the development of our products; effectiveness of our sales force; competition and its effect on pricing, spending, third-party relationships and revenues; dependence on third parties for supplies, particularly for histrelin, manufacturing, marketing, and clinical trials; risks associated with being a manufacturer of some of our products; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO, VANTAS, SUPPRELIN LA and VALSTAR ; reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity, changes in reimbursement policies and/or rates for SANCTURA, VANTAS, SUPPRELIN LA, DELATESTRYL® and any future products; acceptance by the healthcare community of our approved products and product candidates; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly SANCTURA XR, NEBIDO, and VALSTAR; product liability and insurance uncertainties; risks relating to the Redux-related litigation; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this Form 10-Q. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements.

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

Our Business

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

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Our core urology and endocrinology portfolio contains multiple compounds in development in addition to our approved products. Our most advanced compounds are VALSTAR™ for bladder cancer, NEBIDO® for male hypogonadism, PRO 2000 for the prevention of infection by HIV and other sexually-transmitted diseases, and the octreotide implant for acromegaly.

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

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

Recent Product Developments

NEBIDO

On June 27, 2008, we received an approvable letter from the U.S. Food and Drug Administration (FDA) for NEBIDO related to a New Drug Application (NDA) submitted to the FDA in August 2007. The letter indicated that the application may be approved if we are able to adequately respond to certain clinical deficiencies related to the product. The FDA has expressed a concern about a relatively small number of patients in European post-marketing use who have experienced respiratory symptoms immediately following the intramuscular injection of NEBIDO 1000 mg, 4 cc injection volume, (versus the 750 mg, 3 cc injection volume used in the United States). We believe and the FDA concurs that the reaction is likely the result of a small amount of the oily solution immediately entering the vascular system from the injection site, a known, rare complication of oil-based depot injections. The phenomenon is characterized by short-term reactions involving an urge to cough, coughing episodes or a shortness of breath. In rare cases the reaction has been classified as serious or the patient experiences other symptoms such as dizziness, flushing or fainting.

The FDA has requested that we address these clinical deficiencies by providing detailed safety information from clinical studies to determine the precise incidence of serious post-injection oil-based reactions and allergic reactions. Specifically, the FDA has requested follow-up data from the on-going U.S. and European studies in which patients are being treated with NEBIDO on an extended basis. A majority of these trials are scheduled to be completed within twelve months. The FDA stated that depending on the findings, the number of subjects and the number of injections of testosterone undecanoate from the studies listed above, the safety database may need to include data from additional clinical studies. FDA has also requested that we provide a plan to minimize the risks associated with the clinical use of testosterone undecanoate intramuscular injection, namely, to reduce the incidence and/or severity of the serious oil-based reactions and has requested certain in vitro and skin-testing data to exclude an allergic component to the drug or some of its excipients.

We will work with the FDA and our partner, Bayer Schering Pharma AG, to respond to the approvable letter and devise a plan to address the deficiencies. While the FDA has not specifically requested additional clinical studies, we believe that an additional study will likely be required to demonstrate that NEBIDO 750 mg (3 cc volume) administered with careful and proper intramuscular injection technique, has an acceptably low incidence of oil-based reactions to gain approval. We hope to be able to articulate a development plan to address FDA concerns within the next few months. We estimate that it could take approximately 18 months to re-submit the revised NDA.

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

VANTAS

In April 2008, we entered into an agreement to terminate our manufacturing and supply agreement with Shire plc (Shire) related to VANTAS. Under this termination agreement, Shire relinquished its right to receive future royalties on net sales of VANTAS or a percentage of royalties and other consideration received by us relative to a sublicense of our VANTAS selling and marketing rights granted by Shire. In exchange, the termination agreement provided for us to pay Shire a total of $5,000,000 consisting of an immediate payment of $1,000,000 and the balance of $4,000,000 in three annual

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installments commencing in January 2009. We capitalized the net present value of the total $5,000,000 payment using a discount rate of 17.5%, resulting in a $3,900,000 intangible asset. Amortization of the intangible asset is being recognized over the remaining term of the license agreement, which is approximately 6.5 years. After consideration of the $1,000,000 payment, there is approximately $1,000,000 classified as a short-term obligation and $2,100,000 classified as a long-term obligation in the consolidated June 30, 2008 balance sheet. This remaining obligation will be accreted up to its face value over the payment term through charges to interest expense.

In April 2008, we entered into a License, Supply and Distribution Agreement with Orion Corporation (Orion) granting Orion the rights to market VANTAS throughout Europe as well as in certain other countries. VANTAS is currently approved for the treatment of advanced prostate cancer in Denmark and the United Kingdom. VANTAS is currently undergoing the mutual recognition procedure for further European approvals. We received a $7,000,000 up-front payment and could receive certain contingent payments related to approvals and sales thresholds aggregating up to $14,000,000. The $7,000,000 up-front payment represents all amounts we have received to date under the Agreement. Additionally, we have agreed to supply VANTAS to Orion at a pre-determined transfer price subject to annual minimum purchase requirements beginning in 2009. The Agreement expires in April 2023, subject to earlier termination by either party under certain customary conditions of breach. The Agreement will automatically renew for one-year periods at a time, subject to the right of either party to terminate the agreement at any time effective at the end of the initial 15-year term or any subsequent one-year renewal period thereafter with at least six months prior written notice to the other party. Commencing on the first sale of product to Orion, we will recognize the $7,000,000 up-front payment as revenue over the 15-year term of the agreement in accordance with the proportional performance method using the minimum supply quantities to estimate completion of the earnings process. Expected performance will be assessed quarterly to incorporate changes in estimates and milestone payments received.

SANCTURA XR

In September 2007, we entered into an Amended and Restated License, Commercialization and Supply Agreement with Esprit Pharma, Inc. (Esprit), which re-defined the obligations of each party and superseded all previous agreements pertaining to SANCTURA and SANCTURA XR (the Allergan Agreement). The Allergan Agreement became effective on October 16, 2007. Simultaneously, Allergan acquired Esprit resulting in Esprit becoming a wholly-owned subsidiary of Allergan. Upon effectiveness of the Allergan Agreement, we received an up-front license fee, partially creditable by Allergan against future payments to us, of $25,000,000. The Allergan Agreement also grants us the right to receive a fixed percentage of net sales for the term of the Allergan Agreement, subject to increasing annual minimum royalties totaling approximately $123,000,000 over the first seven years of the Allergan Agreement, provided there is no product adverse event, as defined in the Allergan Agreement. Commencing January 1, 2010, or earlier in the case of generic competition, Allergan may reduce, subject to quarterly and annual restrictions, royalty payments by $20,000,000. In addition, we will receive approximately $9,000,000 in annual sales force subsidy for fiscal year 2008 which has been extended to December 31, 2008 and which can be extended to March 31, 2009 at our option. Third-party royalties payable by us as a result of existing licensing, manufacturing and supply agreements associated with sales of SANCTURA and SANCTURA XR will be reimbursed to us. We will also manufacture and supply SANCTURA XR through approximately August 2008, and SANCTURA through September 30, 2012, to Allergan at cost. We may also receive a long-term commercialization milestone payment of $20,000,000 related to generic competition. The Allergan Agreement expires on the later of the twelfth annual anniversary of the launch of SANCTURA XR, which occurred in January 2008, or the date of the last to expire patent covering SANCTURA XR in the United States. Either party may also terminate the Allergan Agreement under certain customary conditions of breach.

In May 2008, together with Madaus, we licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, we received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The performance period continues through September 30, 2012. All consideration received from Allergan during the term will be recognized using the CAPM over the performance period.

Collectively through June 30, 2008 and pursuant to all agreements between us and PLIVA d.d. (PLIVA), Esprit and Allergan, we have received approximately $351,000,000 in the form of up front and milestone payments, royalties, sales force reimbursements and payments for product shipped to our marketing partners at our cost to manufacture.

VALSTAR

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

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

IP 751

In October 2007, we licensed our worldwide rights to IP 751 to Cervelo and received an upfront payment of $1,000,000. In the three month period ended June 30, 2008, we recognized this payment as contract and license fee revenue upon completion of our obligations to Cervelo. In addition, we could receive further payments based on regulatory and, if approved for marketing, commercial achievements aggregating approximately $37,000,000, and royalties based upon net sales. Cervelo is responsible for all future development, manufacturing, marketing and financial obligations relating to IP 751. This agreement will terminate ten years after first commercial sale on a country-by-country basis and may be terminated by either party under certain customary conditions of breach and by Cervelo upon six months notice to us.

PRO 2000

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

ALKS 27

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

Other Recent Developments

In June 2008, we announced that Glenn L. Cooper, M.D. is postponing his previously-announced retirement to lead Indevus through the challenges it faces as a result of the recent delay in the approval of NEBIDO.

Additionally, in June 2008, our Board of Directors approved a revised operating plan that more appropriately aligns our cost structure to our revenue projections and development opportunities. The new operating plan provides for 1) aggressive support and top-line growth of marketed products, VANTAS and SUPPRELIN LA, 2) aggressive support for the launch of VALSTAR for bladder cancer later this year, 3) continued co-promotion with Allergan of SANCTURA and SANCTURA XR with the urology sales force through March 2009, 4) initiation of Phase III trials for the six-month octreotide implant for acromegaly, 5) performance and assessment of responses related to additional NEBIDO clinical studies and 6) significant reduction in operating expenses through a combination of headcount reductions of approximately 12 percent of employees, primarily at the corporate and administrative levels at the Lexington, Massachusetts headquarters, and reduction of other operating expenses. During the three month period ended June 30, 2008, we recorded a charge of approximately $3,500,000 in connection with restructuring actions.

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Critical Accounting Policies and Estimates

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

Goodwill and Other Intangible Assets

Our intangible assets consist primarily of goodwill, VANTAS, our patented HYDRON® Polymer Technology and the Shire technology. The HYDRON Polymer Technology is a proprietary, subcutaneous, retrievable, non-biodegradable, hydrogel reservoir-based drug delivery process involving a device designed to be inserted under a patient s skin allowing the release of drugs continuously, at even, controlled rates for periods up to twelve months (the HYDRON Technology). SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, requires that an intangible asset subject to amortization be reviewed for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. We did not record any impairment charges related to intangible assets during the three or nine months ended June 30, 2008. SFAS 142, *Goodwill and Other Intangible Assets,* requires that periodic tests of goodwill for impairment be performed and that the other intangibles be amortized over their useful lives unless those lives are determined to be indefinite. SFAS 142 requires that goodwill be tested for impairment under a two-step impairment process at least annually or more frequently whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. We performed the required annual impairment assessment of goodwill in the three month period ended June 30, 2008, and we did not record any impairment charges.

We amortize the carrying value of the VANTAS and the HYDRON Technology assets using the straight-line method over useful lives of 14 years for VANTAS, 17 years for the HYDRON Technology and approximately 6.5 years for the VANTAS license. Annual amortization expense is expected to be approximately $2,500,000 for each of the next 5 years. For the three and nine months ended June 30, 2008, we recognized $637,000 and $1,630,000, respectively of amortization expense.

Revenue Recognition Policy

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

Royalty revenue consists of payments received from licensees for a portion of the sales proceeds from products that utilize our licensed technologies. Royalties are generally reported to us in a royalty report on a specified periodic basis and recognized in the period in which the sales of the product or technology on which the royalties are based occurred. If the royalty report for such period is received subsequent to the time when we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

Contract and license fee revenue consists of sales force subsidies, grants from agencies supporting research and development activities, and contractual initial and milestone payments received from partners, as well as amortization of deferred revenue from contractual payments, and since October 2007, sales of SANCTURA and SANCTURA XR product. Our business strategy includes entering into collaborative license, development, supply and co-promotion agreements with strategic partners for the development and commercialization of our products or product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments resulting from the achievement of certain milestones and royalties on net product sales.

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

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

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

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

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

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

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

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After consideration of the estimated performance periods as noted above, we amortized $11,019,000 and $3,562,000 of deferred revenue into contract and license fee revenue during the three and nine months ended June 30, 2008 and 2007, respectively. We amortized $29,930,000 and $12,771,000 of deferred revenue into contract and license fee revenue during the nine months ended June 30, 2008 and 2007, respectively. The balance of deferred revenue related to the Allergan Agreement at June 30, 2008 was $174,976,000.

In May 2008, together with Madaus, we licensed to Allergan the exclusive right to develop, manufacture, and commercialize SANCTURA XR in Canada. In exchange, we received an upfront payment of $7,000,000 and could receive milestone payments totaling $2,000,000 upon achievement of certain sales thresholds. In addition, third-party royalties owed by us on net sales in Canada will be reimbursed by Allergan. This agreement will expire after the later of the expiration of the last applicable patent or our third party royalty obligation, after which Allergan will have a fully-paid license. The performance period continues through September 30, 2012. All consideration received from Allergan during the term will be recognized using the CAPM over the performance period. We amortized $135,000 of deferred revenue into contract and license fee revenue during the three and nine months ended June 30, 2008. The balance of deferred revenue related to this license at June 30, 2008 was $6,865,000.

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

Redux-Related Liabilities

At June 30, 2008, we have an accrued liability of approximately $500,000 for Redux-related expenses, including legal expenses. The amounts we ultimately pay could differ significantly from the amount currently accrued at June 30, 2008. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

Insurance Claim Receivable

As of June 30, 2008, we had an outstanding insurance claim of approximately $3,300,000, consisting of payments made by us to the group of law firms defending us in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of our current outstanding insurance claim is made pursuant to our product liability policy issued to us by Reliance Insurance Company (Reliance). During March 2008, we received a partial payment of $400,000 from Reliance pertaining to this claim. Based upon discussions with our attorneys and other consultants regarding the amount and timing of potential collection of our claim on Reliance, we previously recorded a reserve against our outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of $858,000 reflecting our best estimate given the available facts and circumstances. We believe our reserve of approximately $2,400,000 against the insurance claim on Reliance as of June 30, 2008 is a significant estimate reflecting management s judgment. To the extent we do not collect the insurance claim receivable of $858,000 we would be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

Cash, Cash Equivalents and Marketable Securities

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

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Inventory Capitalization Policy

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

Accounting for Stock-Based Compensation

We have several stock-based employee compensation plans. On October 1, 2005, we adopted SFAS 123R, *Accounting for Stock-Based Compensation* (SFAS 123R). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. We are required to make significant estimates related to SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended June 30, 2008 and 2007, we used a weighted-average expected stock-price volatility of 49.0% and 51.9%, respectively. For stock option grants issued to non-executives during the nine months ended June 30, 2008 and 2007, we used a weighted-average expected stock-price volatility of 49.0% and 53.8%, respectively. We did not issue any stock option grants to executives during the three months ended June 30, 2008 and 2007. In addition, we did not issue any stock option grants to executives during the nine months ended June 30, 2008. For stock option grants issued to executives during the nine months ended June 30, 2007, the Company used a weighted average expected stock-price volatility of 62.8%. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended June 30, 2008 and 2007, we used a weighted-average expected option life assumption of 6.0 and 6.57 years, respectively, for non-executives. For stock option grants made during the nine months ended June 30, 2008 and 2007, we used a weighted-average expected option life assumption of 6.25 and 6.53 years, respectively, for non-executives. For stock option grants made during the nine months ended June 30, 2007, we used a weighted-average expected option life assumption of 8.0 years for executives.

During the three months ended June 30, 2008, the Board of Directors approved modifications to extend the term of certain outstanding fully vested options and we recorded $560,000 of noncash compensation expense related to these modifications. Pursuant to FAS123R, we are required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of stock options.

We have also granted restricted stock units and performance stock awards. The value of these awards is being expensed over the respective vesting period. For the three months ended June 30, 2008 and 2007, we recognized $348,000 and $245,000, respectively, in stock-based compensation. For the nine months ended June 30, 2008 and 2007, we recognized $1,000,000 and $725,000, respectively, in stock-based compensation.

Inclusive of the above stock-based compensation, during the three months ended June 30, 2008 and 2007, we recognized $2,040,000 and $3,267,000, respectively, in total stock-based compensation. During the nine months ended June 30, 2008 and 2007, we recognized $5,316,000 and $5,913,000, respectively, in total stock-based compensation.

Use of Estimates

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

Results of Operations

Our net loss for the three month period ended June 30, 2008 was $(18,964,000), or $(0.25) per share, basic and diluted, a decrease of $53,371,000 from the $(72,335,000), or $(1.02) per share, basic and diluted, reported for the three month period ended June 30, 2007. Our net loss for the nine month period ended June 30, 2008 was $(51,573,000), or $(0.67) per share, basic and diluted, a decrease of $43,500,000 from the $(95,073,000), or $(1.56) per share, basic and diluted, reported for the nine month period ended June 30, 2007. The decreased net loss in the three and nine month periods ended June 30, 2008 is primarily the result of a $50,000,000 non-recurring expense for acquired in-process research and development (IPR&D)

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reflected in the three and nine month periods ended June 30, 2007 as a result of our acquisition of Valera in April 2007. In addition, we experienced lower research and development costs as a result of the conclusion of clinical studies related to SANCTURA, NEBIDO and pagoclone, partially offset by increased sales and pre-marketing expense related to NEBIDO and products obtained through our acquisition of Valera, as well as $3,500,000 of restructuring charges in the three and nine month periods ended June 30, 2008.

Total revenues for the three month period ended June 30, 2008 were $20,419,000, an increase of $8,194,000, or 67%, from the $12,225,000 reported for the three month period ended June 30, 2007. Total revenues for the nine month period ended June 30, 2008 were $54,461,000, an increase of $17,861,000, or 49% from the $36,600,000 reported for the nine month period ended June 30, 2007.

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

Product revenue for the three month period ended June 30, 2008 was $8,221,000, an increase of $1,815,000, or 28%, from the $6,406,000 reported for the three month period ended June 30, 2008. Product revenue for the nine month period ended June 30, 2008 was $22,727,000, an increase of $7,609,000, or 50%, from the $15,118,000 reported for the nine month period ended June 30, 2008. Included in product revenue for the three and nine month periods ended June 30, 2008 is $4,361,000 and $11,520,000, respectively of revenue resulting from the net sales of VANTAS, and $3,498,000 and $8,746,000, respectively, of revenue resulting from the sales of SUPPRELIN LA. This compares to the $2,910,000 of only VANTAS product revenue recorded during the three and nine month periods ended June 30, 2007.

Contract and license fee revenues for the three month period ended June 30, 2008 were $12,198,000, an increase of $6,379,000, or 110%, from the $5,819,000 reported for the three month period ended June 30, 2007. Contract and license fee revenues for the nine month period ended June 30, 2008 were $31,734,000, an increase of $10,252,000, or 48%, from the $21,482,000 reported for the nine month period ended June 30, 2007. The increase in contract and license fee revenue is primarily related to the Esprit and Allergan Agreements including the receipt of a $25,000,000 payment from Allergan in October 2007 which, along with the previously deferred revenue, is now being recognized over a five year CAPM period which replaces the previous twelve year CAPM period applied through October 16, 2007. In addition, product and royalty payments resulting from the Allergan collaboration are accounted for under the CAPM commencing as of the October 16, 2007 effective date of the amended collaboration. Such revenues had previously been reflected as product revenues when the product was shipped and when the royalties were due and payable from Esprit. For the three and nine month periods ended June 30, 2008, we recognized $11,019,000 and $29,930,000 of contract and license fee revenue related to the Allergan Agreement. As of June 30, 2008, we have approximately $174,976,000 of deferred revenue related to the Allergan Agreement which is expected to be recognized under the CAPM through September 30, 2012. We also recognized $135,000 of contract and license fee revenue for the three and nine month periods ended June 30, 2008, related to the Allergan license to manufacture SANCTURA XR in Canada. As of June 30, 2008, we have approximately $6,865,000 of deferred revenue related to this license.

Cost of revenue for the three month period ended June 30, 2008 was $7,837,000, an increase of $4,354,000, or 125%, from the $3,483,000 reported for the three month period ended June 30, 2007. Cost of revenue for the nine month period ended June 30, 2008 was $20,104,000, an increase of $11,071,000, or 123%, from the $9,033,000 reported for the nine month period ended June 30, 2007. Costs associated with sales of SANCTURA and SANCTURA XR increased $2,754,000 and $5,094,000 for the three and nine month periods ended June 30, 2008, respectively, and are consistent with the increased SANCTURA contract and license fee revenue. In addition, costs of goods sold related to higher sales of VANTAS increased $1,136,000 and $6,536,000 for the three and nine month periods ended June 30, 2008, respectively.

Research and development expense for the three month period ended June 30, 2008 was $5,222,000, a decrease of $5,081,000, or (49%), from the $10,303,000 reported for the three month period ended June 30, 2007. Research and development expense for the nine month period ended June 30, 2008 was $17,867,000, a decrease of $11,627,000 or (39%) from the $29,494,000 reported for the nine month period ended June 30, 2007. External product development costs related primarily to SANCTURA XR and Trospium Air decreased approximately $750,000 and $526,000, respectively, in the three month period ended June 30, 2008 and $8,164,000 and $1,361,000, respectively, in the nine month period ended June 30, 2008 because SANCTURA XR was approved in August 2007. External product development costs, including investigator fees and laboratory services, for NEBIDO decreased approximately $1,736,000 in the three month period ended June 30, 2008 and

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$3,206,000 in the nine month period ended June 30, 2008 due to the wind-down of clinical studies. External product development costs related to pagoclone decreased approximately $854,000 in the three month period ended June 30, 2008 and $1,251,000 in the nine month period ended June 30, 2008 due to the conclusion of clinical studies. External product development costs related to PRO 2000 decreased approximately $646,000 in the three month period ended June 30, 2008 and $1,490,000 in the nine month period ended June 30, 2008 due to decreased manufacturing, packaging and labeling costs as ongoing studies are concluding. Partially offsetting these decreased external development costs during the nine months ended June 30, 2008 were increased external product development costs of $3,044,000 incurred for products obtained through our purchase of Valera, including $2,468,000 for VALSTAR, octreotide and stent.

Marketing, general and administrative expense for the three month period ended June 30, 2008 was $20,657,000, an increase of $902,000, or 5%, from the $19,755,000 reported for the three month period ended June 30, 2007. Marketing, general and administrative expense for the nine month period ended June 30, 2008 was $59,699,000, an increase of $18,254,000, or 44%, from the $41,445,000 reported for the nine month period ended June 30, 2007.

Marketing expense for the three month period ended June 30, 2008 was $13,978,000, an increase of $2,939,000, or 27%, from the $11,039,000 reported for the three month period ended June 30, 2007. Marketing expense for the nine month period ended June 30, 2008 was $38,427,000, an increase of $14,550,000, or 61%, from the $23,877,000 reported for the nine month period ended June 30, 2007. This increase is primarily the result of pre-marketing costs related to NEBIDO, which increased approximately $2,402,000 and $4,156,000, respectively, in the three and nine month period ended June 30, 2008, and sales force and other marketing costs, which increased approximately $1,419,000 and $7,268,000 in the three and nine month period ended June 30, 2008, primarily related to the absorption of sales and marketing expenses upon the Valera acquisition. In addition, advertising and marketing expenses for VANTAS and VALSTAR increased approximately $286,000 and $2,640,000 in the three and nine month period ended June 30, 2008, respectively.

General and administrative expense for the three month period ended June 30, 2008 was $6,679,000, a decrease of $2,037,000, or (23%), from the $8,716,000 reported for the three month period ended June 30, 2007. General and administrative expense for the nine month period ended June 30, 2008 was $21,272,000, an increase of $3,704,000, or 21%, from the $17,568,000 reported for the nine month period ended June 30, 2007. Included in the general and administrative expense for the three month period ended June 30, 2008 is decreased stock compensation expense of $847,000 and a decrease of $1,100,000 due to the 2007 one-time charge related to the disposition of our investment in Spepharm Holding B.V., a company specializing in urology products in the European Union. Included in the general and administrative expense for the nine month period ended June 30, 2008 is increased Valera-related employee compensation and benefit expense of approximately $1,430,000 due to the acquisition in April 2007, as well as increased Valera-related facilities expense of approximately $340,000. In addition, legal and professional services fees increased by approximately $1,570,000, as well as executive recruiting fees of approximately $302,000.

In connection with our acquisition of Valera, we allocated $50,000,000 of the purchase price to IPR&D. This IPR&D was expensed at the date of acquisition because the products to which it related had not received regulatory approval and future value was not determinable. Also related to the acquisition of Valera, we acquired certain intangible assets, including VANTAS and the HYDRON Technology. We have recorded amortization expense of $497,000 and $1,490,000 during the three and nine month periods ended June 30, 2008, respectively, and $414,000 for the three and nine months ended June 30, 2007 related to these intangible assets. The annual amortization of these intangible assets is expected to be approximately $2,000,000. The estimated life of these intangible assets is fourteen to seventeen years. We also recorded amortization expense of approximately $140,000 related to the VANTAS license received upon termination of our manufacturing and supply agreement with Shire. The annual amortization of this intangible asset is expected to be approximately $500,000. The estimated life of this intangible asset is the remaining term of the license agreement, which is approximately 6.5 years.

As discussed in Note L, to the Consolidated Financial Statements, on June 30, 2008, we announced a restructuring of operations to more appropriately align our cost structure to revenue projections and development opportunities. As a result of this restructuring, we recorded a charge of approximately $3,500,000 related primarily to separation costs of approximately $2,300,000 and an impairment charge of approximately $1,200,000 associated with the disposal of capital assets. The separation costs of $2,300,000 are expected to be paid through June 2009.

Investment income for the three month period ended June 30, 2008 was $390,000, a decrease of $298,000, or (43%), from the $688,000 reported for the three month period ended June 30, 2007. Investment income for the nine month period ended June 30, 2008 was $2,159,000, a decrease of $432,000, or (17%), from the $2,591,000, reported for the nine month period ended June 30, 2007. The decrease in investment income in the three and nine month periods ended June 30, 2008 is the result of lower average interest rates and lower average funds available for investment.

Interest expense relates primarily to our $71,925,000 of 6.25% Convertible Senior Notes due July 2009 and $75,000 of 6.25% Convertible Senior Notes due July 2008 (the Convertible Notes). Interest expense of approximately $1,891,000 for

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the three months ended June 30, 2008 includes approximately $1,125,000 of interest to be paid, approximately $83,000 of amortization of original debt issuance costs, and approximately $548,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value. Interest expense of approximately $5,364,000 for the nine months ended June 30, 2008 includes approximately $3,375,000 of interest to be paid, approximately $247,000 of amortization of original debt issuance costs, and approximately $1,600,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

At June 30, 2008 we had consolidated cash and cash equivalents of $52,624,000 compared to consolidated cash and cash equivalents of $71,142,000 at September 30, 2007. This decrease of $18,518,000 is primarily the result of net cash used in operating activities of $17,237,000 (see Analysis of Cash Flows).

We are continuing to invest substantial amounts in the ongoing development of our product candidates and sales activities related to our marketed products SANCTURA and SANCTURA XR, SUPPRELIN LA and VANTAS. If approved by the FDA, we expect to invest in launch and marketing activities related to VALSTAR. We are continuing to invest in the development of NEBIDO. We believe our current and expected cash resources are sufficient to fund our operations through approximately June 2009. We will need to obtain additional funding through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to us. The failure to raise such funds would result in the need to significantly curtail our operating activities and delay development efforts, which would have a material adverse effect on us.

We will require additional funds or corporate collaborations for the development and commercialization of our other product candidates, as well as any new businesses, products or technologies acquired or developed in the future. We have no commitments to obtain such funds. There can such be no assurance that we will be able to obtain additional financing to satisfy future cash requirements on acceptable terms, or at all. If such additional funds are not obtained, we may be required to delay product development and business development activities.

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

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

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

Product Development

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

Total research and development expenses incurred by us through June 30, 2008 on our core development products for which an NDA has not been filed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: $24,984,000 for PRO 2000 and $4,776,000 for the octreotide implant. We have not included compounds in development for which we do not expect to incur additional material research and development costs. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be

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substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA.

Given the above uncertainties, and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from June 30, 2008 through the preparation of an NDA for our core development compounds as follows: approximately $14,000,000 for PRO 2000 and $12,000,000 for the octreotide implant. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. When we acquired Valera on April 18, 2007, the following products were in development and unapproved: SUPPRELIN LA, the octreotide implant and the biodegradable ureteral stent. SUPPRELIN LA was approved in May 2007 and the other products are continuing under development. We are currently considering strategic partners for future development and commercialization of PRO 2000 and evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

Analysis of Cash Flows

Net cash used in operating activities

For the nine months ended June 30, 2008, our primary source of funds was related to our agreements with Allergan and Esprit. On the effective date of the Allergan Agreement, we received an up-front fee of $25,000,000. Cash was expended primarily in the normal operations of our business by the various functions as represented in the statement of operations. Net cash used in operating activities in the nine month period ended June 30, 2008 of $17,237,000 consisted primarily of (i) the net loss of $51,573,000, (ii) an increase in accounts receivable of $3,585,000 due to the timing of receipt of customer payments, and (iii) an increase in inventories of $2,773,000 due to the purchase of trospium active pharmaceutical ingredient. This was partially offset by (i) a $31,316,000 increase in deferred revenue primarily due to payments from Allergan, net of amortization, and (ii) $12,404,000 of noncash charges for stock-based compensation, loss on disposal of property, plant and equipment, lease abandonment, inventory impairment, depreciation and amortization and note discount amortization.

For the nine months ended June 30, 2007, net cash used in operating activities of $37,743,000 consisted primarily of the net loss of $95,073,000, partially offset by a non-cash charge of $50,000,000 for acquired IPR&D. Also offsetting the uses of cash in operating activities was non-cash charges of $9,536,000, including stock-based compensation of $5,913,000, and an increase in accrued expenses and other liabilities of $3,310,000. The increase in accrued expenses and other liabilities was primarily due to an increase in general business activities, including activities related to our acquisition of Valera. Contributing to cash used in operating activities was a $2,239,000 increase in accounts receivable primarily due to our shipment of approximately $1,000,000 of SUPPRELIN LA and the timing of payments received from our SANCTURA marketing partner.

Net cash used in operating activities of $17,237,000 for the nine months ended June 30, 2008 decreased $20,506,000 from $37,743,000 for the nine months ended June 30, 2007. The change in deferred revenue between the nine months ended June 30, 2008 and the nine months ended June 30, 2007 resulted in an improvement in cash used in operations of $33,152,000 as there was an increase in deferred revenue from receipts from Allergan in the first three quarters of fiscal 2008. Pursuant to the Allergan Agreement, all payments received from Allergan, including upfront fees, sales force payments, product sales and royalties, are now accounted for as a single unit of accounting and are reflected as contract and license fee revenue in our income statement using the CAPM, which increased our deferred revenue balance approximately $51,218,000 over the nine months ended June 30, 2007. This was partially offset by a decrease in accrued expenses and other liabilities of $7,393,000, primarily related to a reduction in research and development costs associated with NEBIDO, pagoclone and SANCTURA XR.

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Net cash (used in) provided by investing activities

For the nine months ended June 30, 2008, net cash used in investing activities of $(3,822,000) resulted from purchases of property, plant and equipment of approximately $2,822,000 and the initial payment of approximately $1,000,000 to Shire for termination of the manufacturing and supply agreement.

For the nine months ended June 30, 2007, net cash provided by investing activities of $8,609,000 was primarily comprised of (i) maturities and sales of marketable securities of $5,956,000 and (ii) cash acquired net of business acquisition costs of $3,130,000 which consisted of $7,584,000 of cash acquired in the Valera acquisition less $4,454,000 of expenditures related to the acquisition consisting primarily of investment banking, legal, accounting and other professional services and fees.

Net cash used in investing activities of $(3,822,000) for the nine months ended June 30, 2008 increased $12,431,000 from net cash provided by investing activities of $8,609,000 for the nine months ended June 30, 2007 due primarily to the prior year sale of marketable securities of $5,956,000 and the receipt of cash of $3,130,000 related to the acquisition of Valera during the third quarter of 2007.

Net cash provided by financing activities

For the nine months ended June 30, 2008, net cash provided by financing activities of $2,541,000 resulted from common stock issued from exercises of stock options and employee participation in our employee stock purchase plan. We cannot predict if or when stock options will be exercised in the future.

For the nine months ended June 30, 2007, net cash provided by financing activities of $1,042,000 was the result of common stock issued from employee exercises of stock options and employee participation in our employee stock purchase plan during the nine months ended June 30, 2007. We cannot predict if or when stock options will be exercised in the future.

Net cash provided by financing activities of $2,541,000 for the nine months ended June 30, 2008 increased $1,499,000 from $1,042,000 for the nine months ended June 30, 2007 due primarily to increased exercises of stock options and participation in our employee stock purchase plan.

Recent Accounting Pronouncements

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

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

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

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* (SFAS 141R). SFAS 141R replaces SFAS 141, *Business Combinations* (SFAS 141). SFAS 141R retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree; b) recognizes and measures the goodwill

acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R will apply prospectively to

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business combinations for which the acquisition date is on or after our fiscal year beginning October 1, 2009. While we have not yet evaluated this statement for the impact that SFAS 141R will have on our consolidated financial statements, we will be required to expense costs related to any acquisitions after September 30, 2009.

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

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

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

In April 2008, the FASB Staff Position (FSP) issued SFAS No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP SFAS 142-3). FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. The intent of FSP SFAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business Combinations*, and other U.S. generally accepted accounting principles (GAAP). FSP SFAS 142-3 is effective for fiscal years beginning after December 15, 2008 and will be adopted by us in the first quarter of fiscal year 2009. We are currently evaluating the effect that the adoption of FSP SFAS 142-3 will have on our results of operation and financial position or cash flows, but does not expect it to have a material impact.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU 411, *the Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS 162 to have a material effect on our results of operations and financial condition.

In May 2008, the FASB issued FSP Accounting Principles Board (APB) 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP ABP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and (conversion option) components of the instrument in a manner that reflects the issuer s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis and will be adopted by us in the first quarter of fiscal year 2009. We are currently evaluating the potential impact, if any, of the adoption of FSP APB 14-1 on our results of operations and financial condition.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

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

We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars and are subject to interest rate risk, and could decline in value if interest rates fluctuate. Our investment portfolio includes

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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 $106.26. 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 $115.35. The two examples provided above are only hypothetical and actual changes in the value of the Convertible Notes due to fluctuations in the market value of our Common Stock or interest rates could vary substantially from these examples.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of June 30, 2008, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of June 30, 2008 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Changes in Internal Control Over Financial Reporting

Subject to the qualifications set forth below, no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Product Liability Litigation. On September 15, 1997, we announced a market withdrawal of our first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by Wyeth (formerly American Home Products Corporation), our licensee, in June 1996. The withdrawal of Redux was based on a preliminary analysis by the FDA of potential abnormal echocardiogram findings associated with certain patients taking Redux or the combination of fenfluramine with phentermine. After the withdrawal of Redux, we were named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purported to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. To date, there have been no judgments against us, nor have we paid any amounts in settlement of any of these claims.

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

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

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

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

Item 1A. Risk Factors

A restated description of the risk factors associated with our business is set forth below. This description includes any material changes to and supersedes the descriptions of the risk factors associated with our business previously disclosed in Part II, Item 1A of our Quarterly Report on Form 10-Q for our fiscal period ended December 31, 2007. The following factors should be reviewed carefully, in conjunction with the other information contained in this Report and our consolidated financial statements. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this Form 10-Q and presented elsewhere by our management from time to time. See Part I Note Regarding Forward Looking Statements.

Risks Relating to Our Business

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

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

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

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

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Our product candidates may not be successfully developed or achieve market acceptance.

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

In June 2008, the FDA required that we respond to certain clinical deficiencies related to NEBIDO. We are unable to predict when or if we will be able to adequately address the issues raised by the FDA and cannot predict when or if NEBIDO will be approved for marketing by the FDA. The FDA could require additional testing prior to FDA approval. In addition, if approved, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of NEBIDO. Even if NEBIDO receives regulatory clearance, there can be no assurance that it will achieve or maintain market acceptance. If NEBIDO does not achieve market acceptance it will have a material adverse effect on our business and results of operations.

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

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

We will need additional funds in the near future.

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

- marketing success of SANCTURA, SANCTURA XR, VANTAS and SUPPRELIN LA;
- approval, launch and marketing success of VALSTAR;
- the costs and progress of our research and development programs;
- the timing and cost of obtaining regulatory approvals; and
- the timing and cash flows of in-licensing or out-licensing products.

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

We may seek or receive additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for our business and no assurance can be given that the terms of any such transaction

would be favorable to us or our security holders. If we raise additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a negative effect on our stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price.

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

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

At June 30, 2008, we had $72,000,000 of outstanding debt reflected on our balance sheet relating to the Convertible Senior Notes. There currently are $71,925,000 of Notes outstanding with a maturity date of July 15, 2009.

The noteholders may decide not to convert the Notes. If the price of our common stock at the time the Notes become due does not exceed $8.50 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 holders of the Notes in cash on the July 2009 due date.

We may incur additional indebtedness in the future and the 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 Notes or any other notes that may be issued;
- to sell selected assets; or
- to reduce or delay planned expenditures on clinical trials, and development and commercialization activities.

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

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

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

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

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

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

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

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

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

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

- SUPPRELIN LA competes against Abbott Laboratories Products Lupron Depot-PED;

- VALSTAR, if approved and launched, is expected to be the only product approved by the FDA for the treatment of bacillus Calmette-Guerin (BCG)-refractory carcinoma in situ (CIS) of the urinary bladder; and

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

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

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

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

- the success of competing products, including generics; and

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

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

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

We are currently dependent on third parties to manufacture SANCTURA XR, Madaus GmbH (Madaus) to manufacture SANCTURA, and Bayer Schering Pharma AG, Germany (BayerSchering) to manufacture NEBIDO. In addition, we will be dependent on third parties for manufacturing of VALSTAR. We are also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR, as well as for the packaging of SANCTURA and SANCTURA XR. If Madaus or any of these third parties were unable to achieve or maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., we would need to seek alternative sources of supply, which could create disruptions in the supply of

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SANCTURA, SANCTURA XR or NEBIDO. In addition, we are reliant on third parties for manufacturing relating to our non-core product candidates, such as PRO 2000 and pagoclone. Reliance on third-party manufacturers for the manufacture of most of our products, entails risks to which we would not be subject if we manufactured these products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for us.

Any manufacturing facilities for any of our compounds are subject to FDA inspection both before and after NDA approval to determine compliance with U.S. current Good Manufacturing Practices (cGMP) requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing our products. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or commercialize them. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with cGMP. For example, our third-party manufacturer of VALSTAR failed to pass a recent cGMP compliance inspection and as a result, we received a non-approvable letter for VALSTAR which has delayed the approval and launch of this product. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA

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

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

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

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

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

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

Any interruption in the supply or manufacturing of our products or product candidates may adversely impact sales of our products or the development of our product candidates. Any lack of supply during such the period of such interruption may have an adverse impact on our future sales because physicians may have elected to use alternative treatments during this

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

Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

We may also encounter problems with the following:

- production yields;
- raw materials;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;
- changes in FDA requirements;
- controlling production costs; and
- development of advanced manufacturing techniques and process controls.

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

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

To continue to develop products, apply for regulatory approvals and commercialize products, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Certain of our requirements for supplies or clinical compounds are filled by purchase

orders on an as-requested basis and are not the subject of long-term contracts. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of these products or product candidates on reasonable terms or at all.

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

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

obtain and enforce patent protection on our products and technologies;

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

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

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

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

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

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

to enforce any of our patents;

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

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

The products marketed by us or our licensees or being developed by us may infringe patents issued to competitors, universities or others. Third parties could bring legal actions against us or our sublicensees claiming patent infringement and seeking damages or to enjoin manufacturing

and marketing of the affected product or the use of a process for the manufacture of such products. If any such actions are successful, in addition to any potential liability for indemnification, damages and attorneys fees in certain cases, we could be required to obtain a license, which may not be available, in order to continue to

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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.

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

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

We cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products we may develop or, if already available, in particular VANTAS, will not be decreased in the future. 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.

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

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

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

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

- perceived safety and efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- our ability to obtain third-party coverage or reimbursement.

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

We rely on the favorable outcome of clinical trials of our product candidates.

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. For example, in June 2008 the delays in obtaining regulatory approval of NEBIDO resulting from the FDA s approvable letter relating to clinical deficiencies resulted in a material adverse impact on our stock price.

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

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

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

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

We have regulatory guidelines and related pricing risks.

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

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

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

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

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

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

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

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

We have product liability exposure and insurance uncertainties related to our products.

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

The outcome of the Redux litigation could materially harm us.

On September 15, 1997, we announced a market withdrawal of our first commercial prescription product, the weight loss medication Redux, which had been launched by American Home Products Corporation, now Wyeth, our licensee, in June 1996. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect our business. In addition, although we are unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against us, our business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions have had, and may continue to have, an adverse effect on the market price of our common stock and on our ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, and to obtain product liability insurance for other products at costs acceptable to us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations.

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

We could be materially harmed if our agreements were terminated.

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

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

We have incurred substantial net losses over the past five fiscal years, including net losses of approximately $31,800,000, $68,200,000, $53,200,000, $50,600,000 and $103,800,000 for fiscal years 2003, 2004, 2005, 2006 and 2007, respectively. At June 30, 2008 we had an accumulated deficit of approximately $628,075,000.

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

We may not be profitable in the future.

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

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

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes Oxley Act of 2002 to report annually on our internal control over financial reporting. If we, or our independent registered public accounting firm, determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers.

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

We may acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management s attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

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

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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 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, Noah D. Beerman, our Chief Business Officer, Mark S. Butler, our Chief Administrative Officer and General Counsel, Michael W. Rogers, our Chief Financial Officer, and Bobby W. Sandage, Jr., our Chief Scientific Officer. Our business could be adversely affected by the loss of any of these individuals. In addition, we rely on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

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

Risks Relating to Our Common Stock and Other Securities

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

Our board of directors has the authority, without further approval of our stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock. 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.

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, SANCTURA XR, VANTAS and SUPPRELIN LA;
- results of clinical studies and regulatory reviews;

marketing approval of NEBIDO;

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marketing approval of VALSTAR;

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

partnerships, corporate collaborations and company acquisitions;

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

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

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

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

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

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

Redux-related litigation developments;

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

general economic conditions.

The high and low sales prices of our common stock as reported by the NASDAQ Global Market were: $12.83 and $0.85 for fiscal 2002, $6.90 and $1.32 for fiscal 2003, $10.25 and $4.86 for fiscal 2004, $7.45 and $2.41 for fiscal 2005, $6.75 and $2.50 for fiscal 2006, $8.06 and $5.58 for fiscal 2007 and $8.22 and $1.19 for the nine month period ended June 30, 2008. 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.

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

The total estimated purchase price pertaining to our merger with Valera has been allocated to Valera s net tangible assets, identifiable intangible assets, in process research and development and goodwill. To the extent the value of goodwill

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or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and the market value of our common stock.

The price for our common stock could be negatively affected if we issue additional shares.

We have outstanding registration statements on Form S-3 relating to the resale of our shares of common stock and on Form S-8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. In addition, shares of our common stock may be issued upon conversion of the contingent stock rights issued in connection with the merger with Valera. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of our common stock.

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

As of June 30, 2008, we had reserved the following shares of our common stock for issuance:

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

- 14,538,843 shares issuable upon exercise of outstanding options, Performance Stock Awards and deferred stock units, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices;

- 2,317,359 shares reserved for grant and issuance under our stock option, stock purchase and equity incentive plans.

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

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

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

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

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

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

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

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

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

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

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In April 2008, the holder of our issued and outstanding 239,425 shares of Series B Convertible Preferred Stock and 5,000 shares of Series C Convertible Preferred Stock exercised its conversion rights and converted all shares of issued and outstanding preferred stock into 622,220 shares of our Common Stock. The issuance of the shares of common stock was made in reliance on Section 3(a)(9) of the Securities Act of 1933, as amended.

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Item 6. Exhibits

(a) Exhibits

3.1	Restated Certificate of Incorporation, as amended (1)
3.2	By-Laws Certificate of Amendment of Restated Certificate of Incorporation, as amended (2)
10.1	Executive Retirement Agreement by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated March 3, 2008. (*) (3)
10.2	Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Noah D. Beerman dated April 11, 2008 (*) (4)
10.3	Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Michael W. Rogers dated April 11, 2008 (*) (4)
10.4	Retention Agreement by and between Indevus Pharmaceuticals, Inc. and Bobby W. Sandage, Jr. dated April 11, 2008 (*) (4)
10.5	Amendment to Executive Retirement Agreement by and between Indevus Pharmaceuticals, Inc. and Glenn L. Cooper, M.D. dated June 11, 2008. (*) (5)
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 (6)
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 (6)
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 (6)
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 (6)

(*) Management contract or compensatory plan or arrangement
(1) Incorporated by reference to Exhibit 3.4 to the Company s Annual Report on Form 10-K filed with the SEC on December 14, 2005 and Exhibit 3.1 to the Company s Quarterly Report on Form 10-Q filed with the SEC on May 9, 2007.
(2) Incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed with the SEC on December 7, 2007.
(3) Incorporated by reference to the Company s Form 8-K filed with the SEC on March 7, 2008.
(4) Incorporated by reference to the Company s Form 8-K filed with the SEC on April 15, 2008.
(5) Incorporated by reference to the Company s Form 8-K filed with the SEC on June 16, 2008.
(6) Filed with this report.

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INDEVUS PHARMACEUTICALS, INC.

Date: August 7, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: August 7, 2008

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

INDEVUS PHARMACEUTICALS, INC.

Date: August 7, 2008

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