INDEVUS PHARMACEUTICALS INC
Form 10-Q
February 08, 2008
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2007

or

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

Commission File No. 0-18728

INDEVUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes ¨ No 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 February 7, 2008**
Common Stock $.001 par value	**76,794,326 shares**

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

INDEX TO FORM 10-Q

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(Amounts in thousands except share data)

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

Total liabilities and stockholders deficit	$ 198,646	$ 183,050

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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

For the three months ended December 31, 2007 and 2006

(Unaudited)

(Amounts in thousands except per share data)

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

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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended December 31, 2007 and 2006

(Unaudited)

(Amounts in thousands)

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

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

Table of Contents

INDEVUS PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

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

Indevus is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. The Company s approved products include 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® for the treatment of hypogonadism. The Company markets its products through an approximately 100-person specialty sales force.

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

In addition to the Company s core urology and endocrinology portfolio, there are multiple compounds outside of its core focus area which the Company either currently outlicenses for development and commercialization, or intends to outlicense in the future. These compounds include 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 the know-how to Novexel S.A. (Novexel) and IP 751 for pain and inflammation for which the Company licensed worldwide rights to Cervelo Pharmaceuticals, Inc. (Cervelo).

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

B. Accounting Policies

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

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

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

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

arrangement as the Company completes its performance obligation,

Table of Contents

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

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

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

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

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

Accounting for Stock-Based Compensation: The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted SFAS 123R, *Accounting for Stock-Based Compensation* (SFAS 123R). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. The Company is required to make significant estimates related to the adoption of SFAS 123R. The Company s expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended December 31, 2007 and 2006, the Company used a weighted-average expected stock-price volatility of 46% and 59%, respectively. For stock option grants to executives during the three months ended December 31, 2007 and 2006, the Company used a weighted average expected stock-price volatility of 50% and 63%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. The Company also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended December 31, 2007 and 2006, the Company used a weighted-average expected option life assumption of 6.25 for non-executives and 8.0 years for executives. A shorter expected term would result in a lower compensation expense.

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

Table of Contents

C. Valera Acquisition

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

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

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

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

	Three months ended December 31, 2006 (Pro forma)
Revenue	$ 16,355,000
Net loss	$ (66,681,000)
Net loss per common share (basic and diluted)	$ (0.88)

D. Inventories

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

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

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

8

Table of Contents

E. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

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

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

F. Basic and Diluted Loss per Common Share

During the three month period ended December 31, 2007, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 359,000 shares of Common Stock at prices ranging from $7.50 to $8.72 with expiration dates ranging up to November 6, 2017. Additionally, during the three month period ended December 31, 2007, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) $71,925,000 of 6.25% Convertible Senior Notes due in 2009 and $75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes), which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008 with respect to the Convertible Notes due in 2008 and through July 15, 2009 with respect to the Convertible Notes due in 2009; (ii) options to purchase 12,765,000 shares of Common Stock at prices ranging from $1.22 to $7.41 with expiration dates ranging up to December 4, 2017; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; (iv) unvested restricted stock with service-based vesting criteria of 350,400 shares and unvested restricted stock awards with service and market-based vesting criteria of 330,350 to 566,300 contingently issuable shares; and (v) unvested deferred stock units with service vesting criteria of 40,000 shares of Common Stock.

During the three month period ended December 31, 2006, securities not included in the computation of diluted earnings per share, because their exercise price exceeded the average market price during the period were options to purchase 1,237,000 shares of Common Stock at prices ranging from $5.92 to $20.13 with expiration dates ranging up to December 19, 2016. Additionally, during the three month period ended December 31, 2006, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) the Convertible Notes, which are convertible into 10,817,000 shares of Common Stock at a conversion price of $6.656 per share and which are convertible through July 15, 2008; (ii) options to purchase 11,014,000 shares of Common Stock at prices ranging from $1.22 to $6.68 with expiration dates ranging up to October 16, 2016; (iii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iv) unvested restricted stock with service-based vesting criteria of 265,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 255,750 to 426,250 contingently issuable shares.

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

G. Agreements

Allergan/Esprit

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

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

Table of Contents

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

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

Plantex

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

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

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

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

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

Table of Contents

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

I. Other

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

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

J. Income Taxes

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

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

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

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

K. Liquidity

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by its competitors of new technological innovations, dependence on key personnel, its ability to protect proprietary technology, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA government regulations and approval requirements, its ability to grow its business and its ability to obtain adequate financing

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

Table of Contents

marketing of its products and will need to raise additional funds through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available to the Company.

L. Recent Accounting Pronouncements

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

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

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

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

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

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

Note Regarding Forward Looking Statements

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

12

Table of Contents

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; 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; need for additional funds and corporate partners, including for the development of our products; history of operating losses and expectation of future losses; uncertainties relating to controls over financial reporting; difficulties in managing our growth; valuation of our Common Stock; risks related to repayment of debts; risks related to increased leverage; general worldwide economic conditions and related uncertainties; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this Form 10-Q. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements.

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

Our Business

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

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

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

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

Recent Product Developments

SANCTURA XR

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

Table of Contents

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

NEBIDO

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

VALSTAR

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

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

IP 751

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

Critical Accounting Policies and Estimates

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

Goodwill and Other Intangible Assets

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

14

Table of Contents

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

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

Revenue Recognition Policy

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

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

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

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

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

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

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

15

Table of Contents

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

We executed the Allergan Agreement effective on October 16, 2007. The terms and conditions of the Allergan Agreement required an assessment of the expected term of the agreement and our obligations thereunder. We assessed the Allergan Agreement pursuant to Emerging Issues Task Force (EITF) Issue Number 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). We determined we had multiple deliverables for which the fair value of each deliverable was not determinable and concluded that the Allergan Agreement represented a single unit of accounting. Our obligations are expected to cease no later than September 30, 2012. Accordingly, commencing on the effective date of the Allergan Agreement, we will recognize the deferred revenue balances that existed on the effective date, and the incremental license payment of $25 million, over the approximately 5-year obligation period. All future payments received from Esprit during the approximately 5-year obligation period, including royalties, sales force reimbursement and product revenue, will be amortized using the Contingency-Adjusted Performance Model (CAPM). All payments received after the approximately 5-year obligation period will be recognized as revenue when earned, provided that there are no remaining obligations.

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

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

Redux-Related Liabilities

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

Insurance Claim Receivable

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

Cash, Cash Equivalents and Marketable Securities

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

Inventory Capitalization Policy

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

16

Table of Contents

Accounting for Stock-Based Compensation

We have several stock-based employee compensation plans. On October 1, 2005, we adopted SFAS 123R Accounting for Stock-Based Compensation (SFAS 123R). Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period. We were required to make significant estimates related to the adoption of SFAS 123R. Our expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which are obtained from public data sources. For stock option grants issued to non-executives during the three months ended December 31, 2007 and 2006, we used a weighted-average expected stock-price volatility of 46% and 59%, respectively. For stock option grants to executives during the three months ended December 31, 2007 and 2006, we used a weighted average expected stock-price volatility of 50% and 63%, respectively. A higher volatility input to the Black-Scholes model increases the resulting compensation expense. We also determined the weighted-average option life assumption based on the exercise patterns that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns. For stock option grants made during the three months ended December 31, 2007 and 2006, we used a weighted-average expected option life assumption of 6.25 for non-executives and 8.0 years for executives. A shorter expected term would result in a lower compensation expense.

Use of Estimates

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

Results of Operations

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

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

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

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

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

17

Table of Contents

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

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

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

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

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

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

Interest expense relates to our $71,925,000 of 6.25% Convertible Senior Notes due in 2009 and $75,000 of 6.25% Convertible Senior Notes due in 2008 (the Convertible Notes). Interest expense of approximately $1,712,000 in the three months ended December 31, 2007 includes $1,125,000 of interest to be paid, approximately $83,000 of amortization of original debt issuance costs, and approximately $503,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 and their face value. Total interest expense in fiscal 2008 is expected to be approximately $6,650,000, and will include $2,150,000 from accretion of the discounted carrying value of the Convertible Notes due in 2009 to their face value.

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

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

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

Table of Contents

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.

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

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

Product Development

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

Total research and development expenses incurred by us through December 31, 2007 on our core development compounds, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: $23,000,000 for PRO 2000, $2,200,000 for the octreotide implant, and $1,300,000 for the biodegradable ureteral stent. We have not included compounds in development for which we do not expect to incur additional material research and development costs. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA.

Given the above uncertainties, and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from December 31, 2007 through the preparation of an NDA for our core development compounds as follows: approximately $14,000,000 for PRO 2000, $9,000,000 for the octreotide implant and $2,000,000 for the biodegradable ureteral stent. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development. When we acquired Valera on April 18, 2007, the following products were in development and unapproved: SUPPRELIN LA, the octreotide implant and the biodegradable ureteral stent. SUPPRELIN LA was approved in May 2007 and the other products are continuing under development. We are currently considering strategic partners for future development and commercialization of PRO 2000 and evaluating commercialization options for pagoclone in parallel with our ongoing development program and preliminary market development activities.

Analysis of Cash Flows

Net cash provided by operating activities in the three month period ended December 31, 2007 of $9,748,000 consisted primarily of (i) a $29,961,000 increase in deferred revenue from payments from Allergan, net of amortization, and (ii) $3,618,000 of

Table of Contents

noncash stock-based compensation, lease abandonment charges and depreciation and amortization, partially offset by (i) the net loss of $14,703,000, (ii) an increase in accounts receivable of $3,177,000 primarily due to increased sales of SUPPRELIN LA and amounts owed per the Allergan Agreement, and (iii) a decrease in accrued expenses and other liabilities of $2,279,000.

Net cash used in investing activities of $451,000 resulted from purchases of property, plant and equipment.

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

Recent Accounting Pronouncements

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

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

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

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Table of Contents

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

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

Risk related to the Convertible Notes

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of December 31, 2007, of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2007 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Changes in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

On May 30, 2001, we entered into an indemnity and release agreement with Wyeth pursuant to which Wyeth agreed to indemnify us against certain classes of product liability cases filed against us involving Redux. Our indemnification covers plaintiffs who initially opted out of

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-

Table of Contents

related product liability cases. The agreement also provides for Wyeth to fund certain additional insurance coverage to supplement our existing product liability insurance. We believe this total insurance coverage is sufficient to address our potential remaining Redux product liability exposure.

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

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

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

ITEM 1A. Risk Factors

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

Risks Relating to Our Business

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

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

In October 2007, Allergan became our new partner with respect to SANCTURA and 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.

22

Table of Contents

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

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

We expect to derive a substantial portion of our long term revenues from the market acceptance of NEBIDO if it is approved. On November 1, 2007 we announced that the FDA accepted for review our NDA for NEBIDO. The FDA Prescription Drug User Fee Act (PDUFA) target action date for NEBIDO is June 27, 2008. On January 22, 2008 we announced that we had submitted additional data to the FDA pertaining to NEBIDO. Although we do not expect there to be a delay in the PDUFA date as a result of this submission, we would be materially adversely affected if we are unable to obtain FDA approval for NEBIDO or if the FDA should require additional testing prior to FDA approval. In addition, the FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse 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 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.

23

Table of Contents

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

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

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

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

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

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

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

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

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

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

- the success of competing products, including generics; and

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

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

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

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

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

Table of Contents

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 effect our operations and financial condition.

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

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

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

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

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

25

Table of Contents

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: