

INDEVUS PHARMACEUTICALS INC  
Form 10-Q  
February 08, 2007  
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, 2006,

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**  
(State or other jurisdiction of  
incorporation or organization)

**04-3047911**  
(I.R.S. Employer  
Identification Number)

**33 Hayden Avenue**  
**Lexington, Massachusetts**  
(Address of principal executive offices)

**02421-7971**  
(Zip Code)

Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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

---

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

	Outstanding at
Class:	February 5, 2007
Common Stock \$.001 par value	56,198,175 shares

---

**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

**INDEX TO FORM 10-Q**

	<b>PAGE</b>
<b>PART I. FINANCIAL INFORMATION (unaudited)</b>	
Item 1. Financial Statements	
<u>Consolidated Balance Sheets as of December 31, 2006 and September 30, 2006</u>	3
<u>Consolidated Statements of Operations for the Three Months ended December 31, 2006 and 2005</u>	4
<u>Consolidated Statements of Cash Flows for the Three Months ended December 31, 2006 and 2005</u>	5
<u>Notes to Unaudited Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	25
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	25
Item 6. <u>Exhibits</u>	26
SIGNATURE	27

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

	December 31,	September 30,
	2006	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 73,367	\$ 70,169
Marketable securities		5,956
Accounts receivable, net	5,417	2,851
Inventories, net	1,585	1,628
Prepaid and other current assets	3,671	2,598
Total current assets	84,040	83,202
Property and equipment, net	904	880
Insurance claim receivable	1,258	1,258
Prepaid debt issuance costs	1,018	1,183
Inventories, net	1,812	3,293
Other assets	2,420	2,491
Total assets	\$ 91,452	\$ 92,307
<b>LIABILITIES</b>		
Current liabilities:		
Accounts payable	\$ 2,384	\$ 2,917
Accrued expenses	12,517	11,026
Accrued interest	2,075	950
Deferred revenue	15,766	13,433
Total current liabilities	32,742	28,326
Convertible notes	72,000	72,000
Deferred revenue	117,561	114,041
Other	2,145	2,144
Minority interest	126	126
<b>STOCKHOLDERS DEFICIT</b>		
Convertible Preferred Stock \$.001 par value, 5,000,000 shares authorized:		
Series B, 239,425 shares issued and outstanding (liquidation preference December 31, 2006 \$3,038)	3,000	3,000
Series C, 5,000 shares issued and outstanding (liquidation preference December 31, 2006 \$506)	500	500
Common Stock, \$.001 par value, 120,000,000 shares authorized; 56,133,831 and 56,040,456 shares issued and outstanding at December 31, 2006 and September 30, 2006, respectively	56	56
Additional paid-in capital	346,296	344,789
Accumulated deficit	(482,974)	(472,675)
Total stockholders deficit	(133,122)	(124,330)
Total liabilities and stockholders deficit	\$ 91,452	\$ 92,307

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



**Table of Contents****INDEVUS PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****For the three months ended December 31, 2006 and 2005****(Unaudited)****(Amounts in thousands except per share data)**

	<b>Three months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Revenues:</b>		
Product revenue	\$ 5,257	\$ 3,429
Contract and license fees	7,894	5,545
<b>Total revenues</b>	<b>13,151</b>	<b>8,974</b>
<b>Costs and expenses:</b>		
Cost of product revenue	4,276	1,870
Research and development	9,919	10,320
Marketing, general and administrative	9,003	8,308
<b>Total costs and expenses</b>	<b>23,198</b>	<b>20,498</b>
Loss from operations	(10,047)	(11,524)
Investment income	1,040	886
Interest expense	(1,292)	(1,292)
<b>Net loss</b>	<b>\$ (10,299)</b>	<b>\$ (11,930)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.18)</b>	<b>\$ (0.25)</b>
<b>Weighted average common shares outstanding:</b>		
Basic and diluted	55,847	47,166

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, 2006 and 2005****(Unaudited)****(Amounts in thousands)**

	<b>For the three months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (10,299)	\$ (11,930)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	66	129
Amortization of convertible note issuance costs	165	165
Noncash stock-based compensation	1,274	1,007
Inventory impairment	1,100	
<b>Changes in assets and liabilities:</b>		
Accounts receivable	(2,566)	739
Inventories	424	13
Prepaid and other assets	238	(57)
Accounts payable	(533)	374
Deferred revenue	5,853	(4,788)
Accrued expenses and other liabilities	2,607	2,367
<b>Net cash used in operating activities</b>	<b>(1,671)</b>	<b>(11,981)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(90)	(43)
Proceeds from maturities and sales of marketable securities	5,956	3,743
Prepaid acquisition costs	(1,240)	
<b>Net cash provided by investing activities</b>	<b>4,626</b>	<b>3,700</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock and treasury stock	243	4
<b>Net cash provided by financing activities</b>	<b>243</b>	<b>4</b>
<b>Net change in cash and cash equivalents</b>	<b>3,198</b>	<b>(8,277)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>70,169</b>	<b>85,098</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 73,367</b>	<b>\$ 76,821</b>

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, 2006.

Indevus Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus currently markets two products through its approximately 80-person specialty sales force and it has six products in development. Indevus marketed products include SANCTURA<sup>®</sup> for overactive bladder, which it co-promotes with its partner Esprit Pharma, Inc. ( Esprit ), and DELATESTRYL (testosterone enanthate) for the treatment of male hypogonadism.

*B. Revenue Recognition*

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

The Company records sales of product as product revenue upon the later of shipment or as title passes to its customer. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

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

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

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





**Table of Contents**

milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations. Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. The Company records such revenue as contract and license fee revenue.

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

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

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

*C. 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, 2006	September 30, 2006
Raw materials	\$	\$
Finished goods	3,397,000	4,921,000
	\$ 3,397,000	\$ 4,921,000

Finished goods at December 31, 2006 and September 30, 2006 consisted of DELATESTRYL. Pursuant to the Company's acquisition of the DELATESTRYL product in 2006, the Company assumed a commitment to purchase approximately \$1.1 million of additional DELATESTRYL from a third-party supplier. As of September 30, 2006, the Company believed that the supplier had defaulted on its obligation under the purchase commitment to deliver the DELATESTRYL and concluded that the Company was no longer obliged by its assumed commitment, which the supplier disputed. The Company subsequently determined that it will be cost beneficial to settle the dispute with the supplier and as a result of recent negotiations has estimated that it will purchase an additional quantity of DELATESTRYL at a cost of approximately \$750,000. The expected addition of inventory with a shelf life exceeding the shelf life of inventory on hand caused the Company to reassess its selling strategy for the inventory on hand. As a result, the Company determined to write down inventory on hand valued at approximately \$1.1 million and record the charge to cost of revenues in the three month period ended December 31, 2006. The Company has classified \$1,812,000 of DELATESTRYL inventory, net of the write-down, as noncurrent.

*D. Basic and Diluted Loss per Common Share*

The calculation of basic earnings per share for the three months ended December 31, 2006 excludes unvested restricted stock with service-based vesting criteria of 265,900 shares. The Company did not have any unvested restricted stock awards outstanding during the three months ended December 31, 2005.

During the three month period ended December 31, 2006, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

convertible through July 15, 2008 because the effect of their conversion would be antidilutive and (ii) options to purchase 1,237,000 shares of Common Stock at prices ranging from \$5.92 to \$20.13 with

**Table of Contents**

expiration dates ranging up to December 19, 2016 because their exercise price exceeded the average market price during the period. 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) 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; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iii) unvested restricted stock with service-based vesting criteria of 265,900 shares and unvested restricted stock awards with service and market-based vesting criteria of 255,750 to 426,250 contingently issuable shares.

During the three month period ended December 31, 2005, securities not included in the computation of diluted earnings per share were as follows: (i) the Convertible Notes convertible into 10,817,000 shares of Common Stock at a conversion price of \$6.656 per share and which are convertible through July 15, 2008 because the effect of their conversion would be antidilutive and (ii) options to purchase 6,573,000 shares of Common Stock at prices ranging from \$4.06 to \$20.13 with expiration dates ranging up to November 29, 2015 because their exercise price exceeded the average market price during the period. Additionally, during the three month period ended December 31, 2005, potentially dilutive securities not included in the computation of diluted earnings per share, because they would have an antidilutive effect due to the net loss for the period, were as follows: (i) options to purchase 5,410,000 shares of Common Stock at prices ranging from \$1.22 to \$3.80 with expiration dates ranging up to October 25, 2015; (ii) Series B and C Preferred Stock convertible into 622,222 shares of Common Stock; and (iii) warrants to purchase 10,000 shares of Common Stock with an exercise price of \$6.19 and with an expiration date of July 17, 2006.

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

*E. Accounting for Stock-Based Compensation*

The Company has several stock-based employee compensation plans. On October 1, 2005, the Company adopted Statement of Financial Accounting Standards ( SFAS ) No. 123R Accounting for Stock-Based Compensation ( SFAS 123R ) using the modified prospective method, which results in the provisions of SFAS 123R only being applied to the consolidated financial statements on a going-forward basis. 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. Stock-based employee compensation expense, excluding portions related to modifications and restricted stock, was \$1,038,000 and \$707,000, for the three months ended December 31, 2006 and December 30, 2005, respectively.

During the three months ended December 31, 2005, the Board of Directors adopted a modification to the Company's stock option plans relating to the retirement of employees and directors who are also reporting persons pursuant to Section 16 of the Securities Exchange Act of 1934. This provision stipulates that awards to such persons who retire after meeting certain age and service requirements may have an extended period of time after retirement to exercise options that were vested at the date of retirement. In the three months ended December 31, 2005, the Company recorded \$300,000 of noncash compensation expense related to this modification. Pursuant to SFAS 123R, the Company is required to record a charge for the change in fair value measured immediately prior and subsequent to the modification of the stock options.

The Company has granted certain restricted and other unvested performance-based Common Stock awards to the Company's executive officers pursuant to the Company's 2004 Equity Incentive Plan. Compensation expense for these awards is recognized over the service period and is recorded as a component of marketing, general and administrative and research and development expense as appropriate. During the three months ended December 31, 2006, \$236,000 of noncash compensation expense related to these stock awards was recognized. There was no such expense in the three month period ended December 31, 2005.

The Company recognized the full impact of its share-based payment plans, including the impact of the charges related to the modifications and restricted stock explained above, in the consolidated statements of income for the three month periods ended December 31, 2006 and December 31, 2005, under SFAS 123R and did not capitalize any such costs on the consolidated balance sheets, as such costs that qualified for capitalization were not material. In the three month periods ended December 31, 2006 and December 31, 2005, the Company recorded \$1,274,000 and \$1,007,000, respectively, of these noncash expenses. Expense recognized in connection with the adoption of SFAS 123R increased the net loss for the three month periods ended December 31, 2006 and December 31, 2005, by \$1,274,000 and \$1,007,000, respectively, and increased basic net loss per share by \$0.02 and \$0.02, respectively. There was no impact in the three month periods ended December 31, 2006 and December 31, 2005 on cash flows from operations or investing and financing activities in connection with recognition of stock-based competition under SFAS 123R. In the three month periods ended December 31, 2006 and December 31, 2005, the Company allocated \$285,000 and \$148,000 to research and development, respectively, and \$989,000 and \$859,000 to marketing, general and administrative expense, respectively.



**Table of Contents**

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model.

Presented below are the weighted average assumptions used to value stock options granted for the periods indicated:

	Three Months Ended December 31, 2006		
	Executives	Non-executives	2005
Option life	8 years	6.25 years	6.25 years
Risk-free interest rate	4.70%	4.70%	4.25%
Stock volatility	62.8%	59.0%	63.0%
Dividend rate	0.0%	0.0%	0.0%

The Company's expected stock-price volatility assumption is based on both current implied volatility and historical volatilities of the underlying stock which is obtained from public data sources.

The Company determined the weighted-average option life assumption based on the exercise behavior that different employee groups exhibited historically, adjusted for specific factors that may influence future exercise patterns.

The risk-free interest rate used for each grant is equal to the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

As of December 31, 2006, there remained approximately \$7,323,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted average period of approximately 1.4 years.

Presented below is the Company's stock option activity:

	Three Months Ended December 31, 2006		Three Months Ended December 31, 2005	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	11,781,378	\$ 4.55	11,848,295	\$ 4.49
Granted	635,000	\$ 6.34	182,000	\$ 2.89
Exercised	(43,375)	\$ 5.59	(3,000)	\$ 1.45
Cancelled	(68,328)	\$ 11.13	(27,605)	\$ 7.37
Outstanding at end of period	12,304,675	\$ 4.60	11,999,690	\$ 4.46
Options exercisable at end of period	9,748,735		9,258,995	
Weighted average fair value of options granted		\$ 4.35		\$ 1.80

During the three months ended December 31, 2006, the Company granted unvested restricted stock awards with service-based vesting criteria of 50,000 shares and unvested restricted stock awards with service and market-based vesting criteria of 45,000 to 75,000 contingently-issuable shares. Service based stock awards granted during the period have a weighted average grant date fair value of \$5.86, the closing price of the Common Stock on the date of the grant. Service and market based stock awards were valued using a lattice model. Service and market based stock awards granted during the period have a weighted average grant date fair value of \$5.88. During the three months ended December 31, 2006, no restricted stock awards vested and as of the end of the period all 265,900 restricted shares awarded and outstanding remained unvested.

At December 31, 2006, there remained approximately \$2,269,000 of compensation expense related to restricted and other performance-based stock awards to be recognized as expense over approximately 2.75 years.

The aggregate intrinsic value of outstanding options as of December 31, 2006 was \$31,100,000, of which \$26,300,000 was related to exercisable options. The intrinsic value of options exercised during the three months ended December 31, 2006 was \$55,000. The intrinsic value of options vested during the three months ended December 31, 2006 was \$645,000. The weighted average contractual life for total options exercisable at

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

December 31, 2006 is approximately 3.8 years.

The aggregate intrinsic value of restricted stock awards outstanding at December 31, 2006 was \$1,888,000 for awards with service based vesting criteria and from \$1,816,000 to \$3,026,000 for contingently issuable awards with service and market based vesting criteria.

**Table of Contents***F. Comprehensive Loss*

Comprehensive loss for the three months ended December 31, 2006 and 2005 is as follows:

	Three Months Ended December 31,	
	2006	2005
Net loss	\$ (10,299,000)	\$ (11,930,000)
Change in unrealized net gain on investments		3,000
<b>Comprehensive loss</b>	<b>\$ (10,299,000)</b>	<b>\$ (11,927,000)</b>

*G. Valera Pharmaceuticals, Inc.**Merger Agreement*

In December 2006, the Company entered into a definitive agreement under which Indevus will acquire Valera Pharmaceuticals, Inc. in a tax-free stock-for-stock merger valued as of January 18, 2007, and as reflected in our Form S-4 filed on January 29, 2007, at approximately \$111,000,000, plus contingent payments of up to \$3.50 per share based on the achievement of future product milestones. Valera is a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products. Valera currently markets VANTAS for advanced prostate cancer and has multiple products in clinical development including SUPPRELIN-LA for central precocious puberty. Valera has filed a New Drug Application (NDA) for SUPPRELIN-LA and under the Prescription Drug User Fee Act (PDUFA), the FDA is expected to complete its review and act upon this NDA submission by May 3, 2007. Other products in development by Valera include a biodegradable ureteral stent for post-kidney stone lithotripsy and an octreotide implant for the treatment of acromegaly.

Under the terms of the agreement, each share of Valera common stock will be exchanged for an amount of Indevus Common Stock based on an exchange ratio to be determined prior to the Valera stockholders' meeting. This exchange ratio will be determined by dividing \$7.75 by the volume weighted average of the closing prices of Indevus Common Stock, which we refer to as the Indevus Common Stock Value, as reported by the Nasdaq Global Market during the 25 trading days ending five trading days prior to the date of the Valera stockholders' meeting. However, if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be fixed at 0.9626 of a share of Indevus common stock for each share of Valera common stock, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be fixed at 1.1766 shares of Indevus common stock for each share of Valera common stock. In addition, each Valera shareholder will receive three contingent stock rights ( CSRs ) relating to three Valera product candidates in various stages of development for each exchanged Indevus share. One CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of SUPPRELIN-LA and the availability of sufficient launch quantities, one CSR is convertible into \$1.00 of Indevus common stock upon FDA approval of the biodegradable ureteral stent and one CSR is convertible into \$1.50 of Indevus common stock upon FDA approval of the octreotide implant. The amount of Indevus common stock into which the CSRs convert will be determined by a formula based on the average stock price of Indevus prior to achievement of the applicable milestones and the CSRs convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of SUPPRELIN-LA and within five years of the closing of the merger in the case of the biodegradable ureteral stent and the octreotide implant.

The merger has been approved by the boards of directors of Indevus and Valera. Closing of the merger is subject to approval of Valera's stockholders, approval of Indevus' stockholders and other customary closing conditions.

The acquisition of Valera will have an impact on the Company's projected cash flows. Assuming that the acquisition is consummated, Indevus believes that its existing cash resources will be sufficient to fund its planned combined operations through November 2007. There are certain events that could add significant additional cash resources to fund the operations of the combined company. Among these events, Indevus may receive, upon FDA approval of SANCTURA XR, a payment of approximately \$35,000,000 from Esprit, payable at Esprit's option, which would add to Indevus' cash resources. FDA approval may occur as early as August 2007, although there can be no assurance that FDA approval can be obtained. If Indevus does not receive the \$35,000,000 payment from Esprit, Indevus would need to obtain additional funding prior to November 2007 through corporate collaborations, strategic combinations or public or private equity or debt financing or a combination of such alternatives. Although Indevus believes it will receive the \$35,000,000 payment if the FDA approves the SANCTURA XR NDA, or would otherwise be able to obtain additional capital to fund its operations, there can be no assurance that the \$35,000,000 payment from Esprit will be received or that additional capital can be obtained on favorable terms or at all. The failure to receive such payment or raise such funds would result in Indevus



## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

significantly curtailing its marketing and operations and delay development efforts, which would have a material adverse effect on Indevus.

### *Co-Promotion Agreement*

Separate from the definitive merger agreement, Indevus and Valera have entered into a co-promotion agreement under which Indevus sales force will co-promote VANTAS in the United States, beginning in January 2007. Terms of the agreement provide Indevus with royalties of 13.5% on sales of VANTAS up to a specified unit level and increases to 30% above the specified level. For sales of VANTAS to specified specialty pharmacy accounts, Indevus will receive royalties of 35%.

### *H. Agreements*

#### *Madaus*

In November 2006, the Company entered into several agreements with Madaus, licensor of SANCTURA to the Company: (i) a License and Supply Agreement and (ii) an amendment to its original license agreement with Madaus, collectively (the Madaus Agreements ). Under the Madaus Agreements, the Company agreed to (a) purchase from Madaus

**Table of Contents**

all required trospium active pharmaceutical ingredient through November 2007 (b) license to Madaus the rights to sell SANCTURA XR in all countries outside of the United States (the Madaus Territory ) except Canada, Japan, Korea and China (the Joint Territory ), (c) pay to Madaus a fee based on the number of capsules of SANCTURA XR sold by the Company in the U.S. through the earlier of August 23, 2014 or upon generic formulations achieving a predetermined market share, (d) supply SANCTURA XR to Madaus for a specified period of time (e) provide development committee support for a defined period and (f) provide future know-how to Madaus.

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

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

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

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

*Novexel*

In December 2006, the Company licensed its know-how related to aminocandin to Novexel, SA ( Novexel ) for an upfront payment of \$1,500,000 and potential future development milestones and royalties on net sales (the Novexel Agreement ). As of December 31, 2006, the \$1,500,000 upfront payment was received and is reflected as deferred revenue pending completion of certain remaining obligations related to the transfer of our aminocandin know-how. Immediately prior to the execution of the Novexel Agreement, Aventis SA, the Company's original licensor of aminocandin to Indevus, assigned the agreement between Aventis and Indevus to Novexel. Effective as of the date of the Novexel Agreement, the Company entered into a termination agreement with Novexel terminating the original agreement between Aventis and Indevus, thereby alleviating the Company from any further development or financial obligation relating to aminocandin. Pursuant to the Novexel Agreement, Novexel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin.

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

In May 2001, the Company entered into the AHP Indemnity and Release Agreement pursuant to which Wyeth agreed to indemnify the Company against certain classes of product liability cases filed against the Company related to Redux (dexfenfluramine), 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



**Table of Contents**

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, 2006, the Company had an accrued liability of approximately \$500,000 for Redux-related expenses, including legal expenses. The amounts the Company ultimately pays could differ significantly from the amount currently accrued at December 31, 2006. To the extent amounts paid differ from the amounts accrued, the Company will record a charge or credit to the statement of operations.

As of December 31, 2006, the Company had an outstanding insurance claim of \$3,700,000, consisting of payments made by the Company to the group of law firms defending the Company in the Redux-related product liability litigation, for services rendered by such law firms through May 30, 2001. The full amount of the Company's current outstanding insurance claim is made pursuant to the Company's product liability policy issued to the Company by Reliance Insurance Company (Reliance). In October 2001, the Commonwealth Court of Pennsylvania granted an Order of Liquidation to the Insurance Commissioner of Pennsylvania to begin liquidation proceedings against Reliance. Based upon discussions with its attorneys and other consultants regarding the amount and timing of potential collection of its claims on Reliance, the Company has recorded a reserve against its outstanding and estimated claim receivable from Reliance to reduce the balance to the estimated net realizable value of \$1,258,000 reflecting the Company's best estimate given the available facts and circumstances. The amount the Company collects could differ from the \$1,258,000 reflected as a noncurrent insurance claim receivable at December 31, 2006. 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.

*J. Other*

Accrued expenses consisted of the following:

	<b>December 31,</b>	<b>September 30,</b>
	<b>2006</b>	<b>2006</b>
Clinical and sponsored research	\$ 4,032,000	\$ 3,889,000
Compensation related	3,282,000	2,836,000
Professional fees	2,152,000	1,402,000
Income taxes	37,000	22,000
Redux related	539,000	559,000
Manufacturing and production costs	1,349,000	1,266,000
Other	1,126,000	1,052,000
	<b>\$ 12,517,000</b>	<b>\$ 11,026,000</b>

Property and equipment at December 31, 2006 and September 30, 2006 are shown net of accumulated depreciation of \$1,638,000 and \$1,572,000, respectively.

*K. Recent Accounting Pronouncements*

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Instruments*, which is an amendment to SFAS No. 133 and SFAS No. 140. SFAS No. 155 allows financial instruments which have embedded derivatives to be accounted for as a whole (eliminating the need to bifurcate the derivative from its host) if the holder elects to account for the instrument as a whole instrument on a fair value basis. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The Company's adoption of SFAS No. 154 effective October 1, 2006, did not have a material impact on its financial statements.

In June 2006, the FASB issued EITF Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation)*. This standard allows companies to present in their statements of

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

income any taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer, such as sales, use, value-added, and some excise taxes, on either a gross (included in revenue and costs) or a net (excluded from revenue) basis. This standard is effective for interim and fiscal years beginning after December 15, 2006. The Company is currently evaluating the potential impact of this issue on the financial statements, but does not believe the impact of the adoption of this standard will be material.

**Table of Contents**

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertain Tax Provisions*, an Interpretation of SFAS Statement 109 ( *FIN 48* ). *FIN 48* clarifies the accounting for uncertain tax positions as described in SFAS No. 109, *Accounting for Income Taxes*, and requires a company to recognize, in its financial statements, the impact of a tax position only if that position is more likely than not of being sustained on an audit basis solely on the technical merit of the position. In addition, *FIN 48* requires qualitative and quantitative disclosures including a discussion of reasonably possible changes that might occur in the recognized tax benefits over the next twelve months as well as a roll-forward of all unrecognized tax benefits. *FIN 48* is effective for fiscal years beginning after December 15, 2006. The Company intends to adopt *FIN 48* beginning October 2007 and is currently evaluating the impact *FIN 48* might have on its consolidated results of operations and financial condition.

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

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

**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

Statements in this Form 10-Q that are not statements or descriptions of historical facts are forward looking statements under Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products, including SANCTURA® (trospium chloride tablets), SANCTURA XR (once-daily SANCTURA) and NEBIDO® (testosterone undecanoate); our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux-related litigation. The words believe, expect, anticipate, intend, plan, estimate or other expressions which predict or indicate future events and trends do not relate to historical matters identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors and elsewhere in, or incorporated by reference into, the Company's Form 10-K for the fiscal year ended September 30, 2006. These factors include, but are not limited to: dependence on the success of SANCTURA, SANCTURA XR and NEBIDO; the early stage of product candidates under development; uncertainties relating to clinical trials, regulatory approval and commercialization of our products, particularly, SANCTURA XR and NEBIDO®; risks associated with contractual agreements, particularly for the manufacture and co-promotion of SANCTURA and SANCTURA XR and the manufacture of NEBIDO; dependence on third parties for manufacturing, marketing and clinical trials; competition; need for additional funds and corporate partners, including for the development of our products; failure to acquire and develop additional product candidates; history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; the ability to obtain the requisite approvals of the stockholders of Indevus and Valera Pharmaceuticals, Inc. to the proposed merger as well as complete the merger; the risk that the businesses of Valera and Indevus will not be integrated successfully; the risk that the cost savings and any other synergies from the merger may not be fully realized or may take longer to realize than expected; market acceptance for the merger and approved products; risks of regulatory review and clinical trials; disruption from the merger making it more difficult to maintain relationships with customers, employees or suppliers; competition and its effect on pricing, spending, third-party relationships and revenues; our reliance on intellectual property and having limited patents and proprietary rights; dependence on market exclusivity; valuation of our common stock; risks related to repayment of debts; risks related to increased leverage; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this Form 10-Q. Except as may otherwise be required by applicable securities laws, we assume no obligation to update any such forward looking statements.

The following discussion should be read in conjunction with our unaudited consolidated financial statements and notes thereto appearing elsewhere in this report and audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2006. Unless the context indicates otherwise, Indevus, the Company, we, our and us refer to Indevus Pharmaceuticals, Inc., and Common Stock refers to the common stock, \$.001 par value per share, of Indevus.

**Our Business**

Indevus Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. We currently market two products through our approximately 80-person specialty sales force and have six products in development. Our marketed products include SANCTURA for overactive bladder, which we co-promotes with our partner Esprit Pharma, Inc., which we refer to in this Form 10-Q as Esprit, and DELATESTRYL (testosterone enanthate) for the treatment of male hypogonadism.

Indevus' core urology and endocrinology portfolio contains four compounds in development in addition to our marketed products SANCTURA and DELATESTRYL. Our most advanced compound is SANCTURA XR, the once-daily formulation of SANCTURA. In October 2006, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to market SANCTURA XR. NEBIDO, for male hypogonadism, is currently in a fully-enrolled, Phase III pharmacokinetic study and we expect to submit an NDA for NEBIDO in mid-2007. PRO 2000, a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases, is in two ongoing Phase III trials. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In addition to our core urology and endocrinology portfolio, we are preparing to begin a Phase III development program for pagoclone, a GABA-A (gamma amino butyric acid) receptor modulator which it is developing for the treatment of persistent developmental stuttering. Our product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which we recently licensed worldwide rights to Novexel S.A, a spin-out company from sanofi-aventis. Indevus also is receiving royalties under a patent we licensed to Eli Lilly & Company based on net sales of Sarafem® in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.





---

## **Table of Contents**

In December 2006 we announced that we have entered into a definitive agreement under which Indevus will acquire Valera Pharmaceuticals, Inc. in a tax-free stock-for-stock merger valued as of January 18, 2007, and as reflected in our Form S-4 filed on January 29, 2007, at approximately \$111,000,000, plus contingent payments of up to \$3.50 per share based on the achievement of future product milestones. Valera is a specialty pharmaceutical company focused on the development and commercialization of urology and endocrinology products and currently markets VANTAS for advanced prostate cancer. Valera also has multiple products in clinical development including SUPPRELIN-LA for central precocious puberty and VALSTAR for the treatment of BCG-refractory bladder cancer.

In December 2006, we entered into a co-promotion arrangement with Valera and in January 2007, pursuant to the co-promotion arrangement, Indevus and Valera began to jointly market Vantas, Valera's product for the palliative treatment of advanced prostate cancer. The companies jointly market Vantas with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States.

## **Recent Product Developments**

### **SANCTURA XR**

In October 2006, we submitted an NDA to the FDA seeking approval for SANCTURA XR to treat patients with overactive bladder. As a result of the submission of the NDA, we received a \$10,000,000 milestone payment from Esprit, our co-promotion partner for SANCTURA and SANCTURA XR in the United States. The Prescription Drug User Fee Act (PDUFA) target action date for SANCTURA XR is August 13, 2007.

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

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

### **NEBIDO**

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

We expect to report results from our ongoing pharmacokinetic trial for NEBIDO in late May or early June 2007. If successful, we expect to file our NDA for NEBIDO during the summer of 2007. All of the data we have seen to date from the open-label pharmacokinetic trial indicates that NEBIDO should meet the FDA's approvability criteria.

### **AMINOCANDIN**

In December 2006, we licensed our know-how related to aminocandin to Novoxel, SA (Novoxel) for an upfront payment of \$1,500,000 and potential future development milestones, including \$2.0 million upon initiation of Phase II clinical trials and other potential milestones totaling

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

an additional \$41 million, as well as royalties on all future sales of aminocandin (the Novoxel Agreement ). Immediately prior to the execution of the Novoxel Agreement, Aventis SA, the original licensor of aminocandin to us, assigned the agreement between Aventis and Indevus to Novoxel. Effective as of the date of the Novoxel Agreement, we entered into a termination agreement with Novoxel terminating the original agreement between Aventis and ourselves,

## **Table of Contents**

thereby alleviating us from any further development or financial obligation relating to aminocandin. Pursuant to the Novoxel Agreement, Novoxel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin. As of December 31, 2006, the \$1,500,000 upfront payment was received and is reflected as deferred revenue pending completion of certain remaining obligations related to the transfer of our aminocandin know-how.

### **ALKS 27**

On January 4, 2007, we announced our joint collaboration with Alkermes, Inc. for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of chronic obstructive pulmonary disease (COPD). Trospium chloride is the active ingredient in SANCTURA. The announcement of this collaboration followed the completion of feasibility work, preclinical studies and a phase 1 study in healthy volunteers. Preliminary results from the phase 1 study showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed. Pursuant to the collaboration arrangement, we and Alkermes share equally in all costs of development and commercialization of ALKS 27 on a worldwide basis.

### **Critical Accounting Policies and Estimates**

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

#### *Expected Term of the SANCTURA Agreement and Deferred Revenue*

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

We have recorded the \$171,000,000 of initial and milestone payments received pursuant to the SANCTURA Agreement as deferred revenue and are amortizing each component into revenue using the contingency-adjusted method over the estimated remaining duration of the SANCTURA Agreement commencing on the date such payments are earned. We believe the estimated term of the SANCTURA Agreement is a significant estimate which affects revenue recognized and the balance of deferred revenue on our balance sheet.

The balance of deferred revenue under the SANCTURA Agreement at December 31, 2006 is \$131,811,000. We will reevaluate our estimate of the expected term of the SANCTURA Agreement when new information is known that could affect this estimate. If we change our estimate of the duration of the SANCTURA Agreement in the future and extend or reduce our estimate of its duration, we would decrease or increase, respectively, the amount of periodic revenue to be recognized from the amortization of remaining deferred revenue.

## **Table of Contents**

### *Insurance Claim Receivable*

As of December 31, 2006, 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 December 31, 2006 is a significant estimate reflecting management's judgment. To the extent we do not collect the insurance claim receivable of \$1,258,000, we would be required to record additional charges. Alternatively, if we collect amounts in excess of the current receivable balance, we would record a credit for the additional funds received in the statement of operations.

### *Redux-Related Liabilities*

At December 31, 2006, 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, 2006. To the extent the amounts paid differ from the amounts accrued, we will record a charge or credit to the statement of operations.

### *Revenue Recognition Policy*

Product revenue consists primarily of revenues from sales of products, commissions and royalties and reimbursements for royalties owed by us to Madaus GmbH ( Madaus ) for SANCTURA. Product revenue also includes revenue earned from shipments of DELATESTRYL, acquired in January 2006 from Savient Pharmaceuticals, Inc. ( Savient ). Royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and are generally reported to us in a royalty report on a specified periodic basis. Royalty revenue is recognized in the period in which the sales of the product or technology occurred on which the royalties are based.

## **Table of Contents**

If the royalty report for such period is received subsequent to the time when we are required to report our results on Form 10-Q or Form 10-K and the amount of the royalties earned is not estimable, royalty revenue is not recognized until a subsequent accounting period when the royalty report is received and when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

We record sales of product as product revenue upon the later of shipment or as title passes to our customer. Sales of DELATESTRYL are reflected net of reserves for returns and allowances.

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

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

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

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

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

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

## **Results of Operations**

Our net loss decreased \$1,631,000, or 14%, to \$(10,299,000), or \$(0.18) per share, basic, in the three month period ended December 31, 2006 from \$(11,930,000), or \$(0.25) per share, basic, in the three month period ended December 31, 2005. The decreased net loss in the three month period ended December 31, 2006 is primarily the result of increased revenue,



**Table of Contents**

including approximately \$3,500,000 from increased SANCTURA contract, license and product revenue and approximately \$630,000 from DELATESTRYL product revenue partially offset by higher cost of product revenue of approximately \$2,400,000.

Total revenues increased \$4,177,000, or 47%, to \$13,151,000 in the three month period ended December 31, 2006 from \$8,974,000 in the three month period ended December 31, 2005. The increase in the three month period ended December 31, 2006 is primarily due to higher contract and license fee revenues resulting from amortization of deferred revenue, including approximately \$2,300,000 related to a \$10,000,000 milestone payment received from Esprit in October 2006, higher shipments of SANCTURA to our marketing partner and net sales of DELATESTRYL.

Product revenues increased \$1,828,000, or 53%, to \$5,257,000 in the three month period ended December 31, 2006 from \$3,429,000 in the three month period ended December 31, 2005. Sales of SANCTURA to our marketing partner increased \$449,000 to \$1,883,000 in the three month period ended December 31, 2006 from \$1,434,000 in the three month period ended December 31, 2005. Sales of SANCTURA to our marketing partner are dependent upon the timing of our partner's orders which can vary from period to period. In January 2007, Esprit informed us that it would not be placing any further orders for SANCTURA during the remainder of our current fiscal year as they manage their SANCTURA inventory closely in anticipation of the FDA's approval of our once-daily product, SANCTURA XR. We therefore do not anticipate any further SANCTURA product sales for the remainder of our current fiscal year. Royalties from SANCTURA increased \$703,000 to \$2,461,000 in the three month period ended December 31, 2006 from \$1,758,000 in the three month period ended December 31, 2005. Royalties in the fiscal 2007 and 2006 periods reflected the minimum royalties due from Esprit for SANCTURA. The minimum royalties increased on an annual basis from \$5,625,000 to \$7,875,000 effective July 1, 2006. We expect royalty revenue from SANCTURA in fiscal 2007 will continue to reflect such minimum royalties, which increase to \$10,500,000 annually for the royalty year commencing July 1, 2007. Esprit's minimum royalty obligation will expire in June 2008. Additionally, product revenue included net sales of DELATESTRYL of \$621,000 in the three-month periods ended December 31, 2006. We commenced selling DELATESTRYL in January 2006.

Contract and license fee revenues relate almost entirely to the SANCTURA Agreement and increased \$2,349,000, or 42%, to \$7,894,000 in the three month period ended December 31, 2006 from \$5,545,000 in the three month period ended December 31, 2005. Included in contract and license fee revenue was \$5,646,000 and \$3,354,000 from amortization of deferred revenue in the three month periods ended December 31, 2006 and 2005, respectively. The fiscal 2007 revenue included approximately \$2,300,000 related to the \$10,000,000 milestone received from Esprit in October 2006 pursuant to our filing the SANCTURA XR NDA. Sales force subsidies pursuant to our SANCTURA agreement with Esprit were approximately \$2,200,000 in each of the three month periods ended December 31, 2006 and 2005.

Cost of product revenue increased \$2,406,000, or 129%, to \$4,276,000 in the three month period ended December 31, 2006 from \$1,870,000 in the three month period ended December 31, 2005. This increase is primarily due to the increases in sales of SANCTURA product sold to our marketing partner at our cost to manufacture and cost of DELATESTRYL sold of \$1,652,000 in the three month period ended December 31, 2006. Included in the DELATESTRYL cost of product sales during the three month period ended December 31, 2006, is a \$1,100,000 write-down of excess inventory as described in Note C to our financial statements.

Research and development expense decreased \$401,000, or 4%, to \$9,919,000 in the three month period ended December 31, 2006 from \$10,320,000 in the three month period ended December 31, 2005. These decreases are primarily due to decreased external product development costs of approximately \$800,000 in the three month period ended December 31, 2006. External development costs related to trospium decreased approximately \$1,800,000 in the three month period ended December 31, 2006, and related primarily to decreased expenses for the Phase III clinical development program for SANCTURA XR initiated in September 2005. Pagoclone external development costs related primarily to our Phase II clinical trial for stuttering decreased approximately \$300,000 in the three month period ended December 31, 2006. Partially offsetting these decreased external development costs are increased NEBIDO external development costs of approximately \$1,400,000 in the three month period ended December 31, 2006 related to the clinical trial commenced after December 31, 2005. Additionally, employee and compensation related expense increased approximately \$100,000 in the three month period ended December 31, 2006, primarily related to increased stock-based compensation expense recognized pursuant to SFAS 123R.

Marketing, general and administrative expense increased \$695,000, or 8%, to \$9,003,000 in the three month period ended December 31, 2006 from \$8,308,000 in the three month period ended December 31, 2005. Marketing expense increased \$246,000, or 5%, to \$4,819,000 in the three month period ended December 31, 2006 from \$4,573,000 in the three month period ended December 31, 2005. The increase in marketing expense in the three month period ended December 31, 2006 included approximately \$250,000 resulting from increased compensation-related expenses, including approximately \$50,000 higher stock-based compensation recognized under SFAS 123R.

---

## **Table of Contents**

General and administrative expense increased \$449,000, or 12%, to \$4,184,000 in the three month period ended December 31, 2006 from \$3,735,000 in the three month period ended December 31, 2005. The change during the three month period included an increase of approximately \$360,000 related to additional personnel cost from new hires and an increase in stock-based compensation. As of December 31, 2006 we have recorded a prepayment of approximately \$1,240,000 primarily representing legal, accounting and valuation services incurred in relation to the Valera acquisition. These costs will be included in the allocation of purchase price if the merger with Valera is consummated, otherwise they will be reflected as general and administrative expense in the fiscal period in which it is determined the merger will not occur.

Investment income increased \$154,000, or 17%, to \$1,040,000 in the three month period ended December 31, 2006 from \$886,000 in the three month period ended December 31, 2005, reflecting higher interest rates and higher average invested balances in the fiscal 2007 periods from the fiscal 2006 periods.

Interest expense of \$1,292,000 in the three month periods relate to our \$72,000,000 of 6.25% Convertible Senior Notes due 2008 (the Convertible Notes ). Annual interest expense is expected to be approximately \$5,200,000, which includes approximately \$700,000 of amortization of debt issuance costs.

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

## **Liquidity and Capital Resources**

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

At December 31, 2006 we had consolidated cash, cash equivalents of \$73,367,000 compared to consolidated cash, cash equivalents and marketable securities of \$76,125,000 at September 30, 2006. This decrease of \$2,758,000 is primarily the result of net cash used in operating activities of \$1,671,000 (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. In particular, we are investing in the development of NEBIDO and will invest in regulatory activities related to a NEBIDO NDA if the currently ongoing pharmacokinetic study is successful. We believe we have sufficient cash for currently planned expenditures for the next twelve months.

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

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

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



**Table of Contents**

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

**Product Development**

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

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

Total research and development expenses incurred by us through December 31, 2006 on the major compounds currently being developed or marketed, including up-front and milestone payments and allocation of corporate general and administrative expenses, were approximately as follows: \$138,000,000 for SANCTURA and SANCTURA XR, \$21,000,000 for NEBIDO, \$19,000,000 for PRO 2000, \$7,000,000 for IP 751, \$11,000,000 for aminocandin and \$35,000,000 for pagoclone. In June 2002, we re-acquired rights to pagoclone from Pfizer Inc. During the period Pfizer had rights to pagoclone, Pfizer conducted and funded all development activities for pagoclone. Estimating costs and time to complete development of a compound is difficult due to the uncertainties of the development process and the requirements of the FDA which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Results of any testing could result in a decision to alter or terminate development of a compound, in which case estimated future costs could change substantially. Certain compounds could benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs. In the event we were to enter into a licensing or other collaborative agreement with a corporate partner involving sharing, funding or assumption by such corporate partner of development costs, the estimated development costs to be incurred by us could be substantially less than the estimates below. Additionally, research and development costs are extremely difficult to estimate for early-stage compounds due to the fact that there is generally less comprehensive data available for such compounds to determine the development activities that would be required prior to the filing of an NDA. Given these uncertainties and other risks, variables and considerations related to each compound and regulatory uncertainties in general, we estimate remaining research and development costs, excluding allocation of corporate general and administrative expenses, from December 31, 2006 through the preparation of an NDA for our major compounds currently being developed as follows: approximately \$9,000,000 for NEBIDO, \$14,000,000 for PRO 2000, approximately \$46,000,000 for IP 751 and approximately \$61,000,000 for pagoclone for stuttering. In December 2006, we entered into the Novoxel Agreement whereby Novoxel now is responsible for all future development, manufacturing, marketing and financial obligations relating to aminocandin. Actual costs to complete any of our products may differ significantly from the estimates. We cannot reasonably estimate the date of completion for any compound that is not at least in Phase III clinical development due to uncertainty of the number, size, and duration of the trials which may be required to complete development.

**Analysis of Cash Flows**

Net cash used in operating activities in the three month period ended December 31, 2006 of \$1,671,000 consisted primarily of the net loss of \$10,299,000 offset partially by increases of \$5,853,000 and \$2,607,000 in deferred revenues and accrued expenses, respectively. The net increase in deferred revenue occurred as a result of our receipt of the \$10,000,000 milestone payment from Esprit related to our October 2006 NDA submission for SANCTURA XR. Also reducing the effect of the operating loss were noncash stock-based compensation of \$1,274,000, reduced inventory of \$424,000 and a decrease in prepaids and other assets of \$238,000 during the three month period ended December 31, 2006. A \$1,100,000 non-cash write down of excess DELATESTRYL inventory, as described in Note C to our financial

**Table of Contents**

statements, also offset a portion of the cash reduction resulting from the net loss. Increases in accounts receivable also contributed to the reduction in cash during the recent period. Accounts receivable increased \$2,566,000 during the three months ended December 31, 2006, primarily as a result of approximately \$1,900,000 of outstanding SANCTURA receivables due from Esprit for product shipped during the three month period ended December 31, 2006.

Net cash provided by investing activities of \$4,626,000 during the three months ended December 31, 2006, is primarily comprised of maturities and sales of marketable securities of \$5,956,000 partially offset by \$1,240,000 of capitalized Valera acquisition costs previously discussed.

Net cash provided by financing activities of \$243,000 were the result of common stock issued from employee exercises of stock options during the three months ended December 31, 2006. We cannot predict if or when stock options will be exercised in the future.

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

The following chart summarizes our contractual payment obligations as of December 31, 2006. The Convertible Notes and license fees are reflected as liabilities on our balance sheet as of December 31, 2006. Operating leases are accrued and paid pursuant to the lease arrangement. Purchase obligations relate to research and development agreements and arrangements; portions of these amounts are reflected as accrued expenses on our balance sheet as of December 31, 2006.

Contractual Obligations	Payments due by Period				Total
	Less than 1 Year	1-3 Years	3-5 Years	Greater than 5 Years	
Convertible Notes	\$	\$ 72,000,000	\$	\$	\$ 72,000,000
Interest on Convertible Notes	4,500,000	3,600,000			8,100,000
Purchase obligations (1)	15,392,000	4,492,000	26,000		19,910,000
Operating leases	1,235,000	2,226,000	969,000		4,430,000
<b>Total</b>	<b>\$ 21,127,000</b>	<b>\$ 82,318,000</b>	<b>\$ 995,000</b>	<b>\$</b>	<b>\$ 104,440,000</b>

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

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

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

Pursuant to our agreement with Savient whereby we acquired DELATESTRYL in January 2006, we assumed a commitment to purchase approximately \$1.1 million of additional DELATESTRYL from a third-party supplier. As of September 30, 2006, we believed that the supplier had defaulted on our obligation under the purchase commitment to deliver the DELATESTRYL and concluded that we were no longer obliged by its assumed commitment, which the supplier disputed. We subsequently determined that it will be cost beneficial to settle the dispute with the supplier and as a result of recent negotiations have estimated that we will purchase an additional quantity of DELATESTRYL at a cost of approximately \$750,000.

## Edgar Filing: INDEVUS PHARMACEUTICALS INC - Form 10-Q

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

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

### **Other**

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Instruments*, which is an amendment to SFAS No. 133 and SFAS No. 140. SFAS No. 155 allows financial instruments which have embedded

**Table of Contents**

derivatives to be accounted for as a whole (eliminating the need to bifurcate the derivative from its host) if the holder elects to account for the instrument as a whole instrument on a fair value basis. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. Our adoption of SFAS No. 154 effective October 1, 2006, did not have a material impact on our financial statements.

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

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertain Tax Provisions*, an Interpretation of SFAS Statement 109 (FIN 48). FIN 48 clarifies the accounting for uncertain tax positions as described in SFAS No. 109, *Accounting for Income Taxes*, and requires a company to recognize, in its financial statements, the impact of a tax position only if that position is more likely than not of being sustained on an audit basis solely on the technical merit of the position. In addition, FIN 48 requires qualitative and quantitative disclosures including a discussion of reasonably possible changes that might occur in the recognized tax benefits over the next twelve months as well as a roll-forward of all unrecognized tax benefits. FIN 48 is effective for fiscal years beginning after December 15, 2006. We intend to adopt FIN 48 beginning October 2007 and are currently evaluating the impact FIN 48 might have on our consolidated results of operations and financial condition.

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

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

**Table of Contents**

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

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

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

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

**Risk related to the Convertible Notes**

The fair value of our Convertible Notes is sensitive to fluctuations in interest rates and the price of our Common Stock into which the Convertible Notes are convertible. A decrease in the price of our Common Stock could result in a decrease in the fair value of the Convertible Notes. For example on a very simplified basis, a decrease of 10% of the market value of our Common Stock could reduce the value of a \$1,000 Note by approximately \$45. 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. 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.

---

## **Table of Contents**

### **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, 2006, 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, 2006 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to ensure that information required to be disclosed by an issuer in the reports that it files under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

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

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

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

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

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

*General.* Although we maintain certain product liability and director and officer liability insurance and intend to defend these and similar actions vigorously, we have been required and may continue to be required to devote significant management time and resources to these legal actions. In the event of successful uninsured or insufficiently insured claims, or in the event a successful indemnification claim were made against us and our officers and directors, our business, financial condition and results of operations could be materially adversely affected. The uncertainties and costs associated with these legal actions have had, and may continue to have an adverse effect on the market price of our common stock and on our



**Table of Contents**

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 6. Exhibits**

(a) Exhibits

- 2.1 Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus Pharmaceuticals Inc., Hayden Merger Sub, Inc., and Valera Pharmaceuticals, Inc. (1)
- 10.1 Voting Agreement, dated as of December 11, 2006, by and among Indevus Pharmaceuticals, Inc., Hayden Merger Sub, Inc. and certain affiliated funds of Sanders Morris Hariss, Inc. (1)
- 10.2 Voting Agreement, dated as of December 11, 2006, by and among Indevus Pharmaceuticals, Inc., Hayden Merger Sub, Inc. and Psilos Group Partners II-S, L.P. (1)
- 10.3 Side Letter dated as of December 11, 2006, by and among Indevus Pharmaceuticals, Inc. and certain affiliated funds of Sanders Morris Harris, Inc. (2)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (3)
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (3)
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Glenn L. Cooper, Chief Executive Officer (3)
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Micheal W. Rogers, Chief Financial Officer (3)

---

(1) Incorporated by reference to Indevus Form 8-K filed December 12, 2006.

(2) Incorporated by reference to Indevus Registration Statement on Form S-4 filed January 29, 2007.

(3) Filed with this report.



**Table of Contents**

**INDEVUS PHARMACEUTICALS, INC.**

INDEVUS PHARMACEUTICALS, INC.

Date: February 7, 2007

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 7, 2007

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

INDEVUS PHARMACEUTICALS, INC.

Date: February 7, 2007

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