Valera Pharmaceuticals Inc
Form 10-Q
November 09, 2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

þ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended: September 30, 2006

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number: 000-51768
VALERA PHARMACEUTICALS, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**13-4119931**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7 Clarke Drive Cranbury, New Jersey	**08512**
(Address of principal executive offices)	(Zip Code)

(609) 235-3000
(Registrant s telephone number, including area code)

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 period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

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 o Accelerated filer o Non-accelerated filer þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

As of November 1, 2006, there were 14,934,807 shares of the registrant s common stock, $0.001 par value outstanding.

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Cautionary Statement Regarding Forward-Looking Statements

We have included, and from time to time may make in our public filings, press releases or other public statements, certain statements, including (without limitation) those under Management s Discussion and Analysis of Financial Condition and Results of Operations in Part I, Item 2 (MD&A), and Quantitative and Qualitative Disclosures about Market Risk in Part I, Item 3 that may constitute forward-looking statements. In addition, our management may make forward-looking statements to analysts, investors, representatives of the media and others. These forward-looking statements are not historical facts and represent only Valera Pharmaceuticals beliefs regarding future events, many of which, by their nature, are inherently uncertain and beyond our control.

The nature of Valera Pharmaceuticals business makes predicting the future trends of our revenues, expenses and net income difficult. The risks and uncertainties involved in our business could affect the matters referred to in such statements and it is possible that our actual results may differ from the anticipated results indicated in these forward looking statements. Important factors that could cause actual results to differ from those in the forward-looking statements include (without limitation):

changes in reimbursement policies and/or rates for Vantas and any future products;

the actions and initiatives of current and potential competitors;

the impact of current, pending and future legislation, regulation and legal actions in the United States and worldwide affecting the pharmaceutical and healthcare industries;

our ability to manufacture our Vantas product; and

our ability to develop products, receive regulatory approvals, and market our products.

Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made. Valera Pharmaceuticals undertakes no obligation to update publicly or revise any forward-looking statements to reflect the impact of circumstances or events that arise after the dates they are made, whether as a result of new information, future events or otherwise except as required by applicable law. You should, however, consult further disclosures Valera Pharmaceuticals may make in future filings of its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and any amendments thereto.

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VALERA PHARMACEUTICALS, INC
BALANCE SHEETS
(in thousands, except par value)

	September 30, 2006 (Unaudited	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,891	$ 2,340
Investments held-to-maturity	2,982	
Accounts receivable, net of allowances of $318 at September 30, 2006 and $385 at December 31, 2005	2,311	4,488
Inventories, net	5,569	3,191
Prepaid expenses and other current assets	841	726
Total current assets	27,594	10,745
Property, plant and equipment, net of accumulated depreciation of $1,788 at September 30, 2006 and $1,374 at December 31, 2005	7,513	4,194
Deferred offering costs		1,378
Intangible assets, net of accumulated amortization of $52 at September 30, 2006	473	
Other non current assets	169	215
Total assets	$ 35,749	$ 16,532
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,233	$ 1,421
Accrued liabilities	2,314	4,607
Note payable		1,525
Deferred revenue current		329
Capital lease obligations current	11	18
Total current liabilities	5,558	7,900
Capital lease obligations long term	15	
Deferred revenue long term	300	300
Commitments and contingent liabilities		
Series A 6% Cumulative Convertible Preferred Stock, $0.001 par value; 0 and 7,000 shares issued and outstanding; liquidation preference $0 and $7,598 at September 30, 2006 and December 31, 2005, respectively		13,604
Series B 10% Cumulative Convertible Preferred Stock, $0.001 par value; 0 and 22,069 shares issued and outstanding; liquidation preference $0 and		15,082

$20,221 at September 30, 2006 and December 31, 2005 respectively		
Series C 6% Cumulative Convertible Preferred Stock, $0.001 par value; 0 and 11,600 shares issued and outstanding; liquidation preference $0 and $12,590 at September 30, 2006 and December 31, 2005, respectively		11,239
Shareholders equity (deficit):		
Common stock, $0.001 par value; 30,000 authorized, 14,935 and 1,667 issued and outstanding at September 30, 2006 and December 31, 2005, respectively	15	2
Additional paid-in-capital	79,060	8,696
Deferred stock-based compensation		(630)
Accumulated deficit	(49,199)	(39,661)
Total shareholders equity (deficit)	29,876	(31,593)
Total liabilities and shareholders equity (deficit)	$ 35,749	$ 16,532

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

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VALERA PHARMACEUTICALS, INC
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three months ended		Nine months ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Net product sales	$ 2,909	$ 3,668	$ 14,649	$ 21,633
Licensing revenue	104	10	116	26
Total net revenue	3,013	3,678	14,765	21,659
Operating costs and expenses:				
Cost of product sales	883	809	3,997	4,783
Research and development	1,880	1,490	5,714	4,411
Selling and marketing	3,226	2,911	9,705	8,232
General and administrative	1,987	1,595	5,598	4,128
Amortization of intangible assets	26		52	
Total operating costs and expenses	8,002	6,805	25,066	21,554
(Loss) income from operations	(4,989)	(3,127)	(10,301)	105
Interest income	269	20	774	49
Interest expense		(1)	(27)	(3)
(Loss) income before income taxes	(4,720)	(3,108)	(9,554)	151
Benefit from income taxes	(36)	(300)	(16)	
Net (loss) income	$ (4,684)	$ (2,808)	$ (9,538)	$ 151
Basic net (loss) income per share	$ (0.31)	$ (1.68)	$ (0.73)	$ 0.09
Diluted net (loss) income per share	$ (0.31)	$ (1.68)	$ (0.73)	$ 0.01
Basic weighted average number of shares outstanding	14,906	1,667	13,123	1,667
Diluted weighted average number of shares outstanding	14,906	1,667	13,123	11,358

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

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VALERA PHARMACEUTICALS, INC
STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)
For the Nine Months Ended September 30, 2006
(in thousands)
(Unaudited)

	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balances at December 31, 2005	1,667	$ 2	$ 8,696	$ (630)	$ (39,661)	$ (31,593)
Net loss					(9,538)	(9,538)
Issuance of common stock from initial public offering	3,863	4	30,201			30,205
Conversion of preferred stock into common stock	9,356	9	39,916			39,925
Exercise of stock options	49		151			151
Elimination of deferred compensation related to adoption of FAS 123(R)			(630)	630		
Expense related to options granted to non-employees			(1)			(1)
Compensation expense related to employee stock options			727			727
Balances at September 30, 2006	14,935	$ 15	$ 79,060	$	$ (49,199)	$ 29,876

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

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VALERA PHARMACEUTICALS, INC
STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2006	**2005**
Operating activities		
Net (loss) income	$ (9,538)	$ 151
Adjustments to reconcile net (loss) income to net cash used in operating activities		
Depreciation and amortization	466	352
Amortization of deferred financing fees	51	
Allowances for accounts receivable	40	206
Expense related to options granted to non-employees	(1)	72
Stock based compensation	727	(56)
Changes in assets and liabilities which provided (used) cash		
Accounts receivable	2,137	(859)
Inventories	(2,378)	(1,564)
Restricted cash		100
Prepaid expenses and other current assets	(115)	(403)
Security deposits		(46)
Accounts payable	1,812	(458)
Accrued liabilities	(2,293)	2,712
Deferred revenue	(329)	300
Net cash (used in) provided by operating activities	(9,421)	507
Investing Activities		
Capital expenditures	(3,705)	(1,722)
Purchase of product rights	(525)	
Purchase of investment in Spepharm	(5)	
Purchase of investments held-to-maturity	(5,982)	
Proceeds from the sale of investment held-to-maturity	3,000	
Net cash used in investing activities	(7,217)	(1,722)
Financing Activities		
Net proceeds from issuance of common stock	31,734	1
Payment of capital lease obligations	(20)	(13)
Payment of notes payable	(1,525)	
Deferred financing costs		(75)
Deferred offering costs		(1,182)

Net cash provided by (used in) financing activities	30,189	(1,269)
Net increase (decrease) in cash and cash equivalents	13,551	(2,484)
Cash and cash equivalents at beginning of period	2,340	5,053
Cash and cash equivalents at end of period	$ 15,891	$ 2,569
Schedule of noncash investing and financing activities:		
Conversion of preferred stock into common stock	$ 39,925	$
Acquisition of an asset through a capital lease	$ 28	$

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

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED

Note 1. Organization and Description of Business

Valera Pharmaceuticals, Inc. (Valera or the Company) is a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize its Hydron implant proprietary technology. The Company s headquarters and manufacturing operations are located in Cranbury, New Jersey. Valera was incorporated in the state of Delaware on May 30, 2000.

Recent Developments

On September 7, 2006, the Company announced that the Food and Drug Administration (FDA) had accepted the submission of its New Drug Application (NDA) for Supprelin®-LA, a 12-month implant for treating central precocious puberty (CPP) or the early onset of puberty in children. Accordingly, under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to complete its review and act upon this NDA submission by the PDUFA required date of May 3, 2007. In November 2005, the FDA granted Supprelin®-LA orphan drug designation, which provides seven years marketing exclusivity from date of marketing approval as well as certain economic benefits and tax credits. The Company also announced in September 2006 that its Supprelin®-LA manufacturing facilities in Cranbury, New Jersey successfully passed a recent FDA pre-approval inspection.

On September 27, 2006, the Company entered into a License and Distribution Agreement with Spepharm Holding B.V. (Spepharm). Under the terms of the agreement, the Company will give Spepharm the exclusive licensing and distributing rights to its products under the trademarks Vantas® and Supprelin® in the European Union as well as Norway and Switzerland for a period of ten years, unless sooner terminated as provided by the agreement. Spepharm will pay the Company for the Company s supply and Spepharm s distribution of the products under the agreement an aggregate amount equal to forty percent (40%) of Net Sales (the Royalty Amount) as defined by the agreement based on an established transfer price. In addition, following the end of each quarter, Spepharm will pay to the Company an amount equal to the difference between (a) the aggregate Royalty Amount for such calendar quarter minus (b) the aggregate transfer prices paid by Spepharm during such calendar quarter.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with the Securities and Exchange Commission s regulations for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and notes required by U.S. generally accepted accounting principles (GAAP) for complete financial statements. The accounting policies the Company follows are set forth in Note 2, *Summary of Significant Accounting Policies,* to the Company s financial statements in its Annual Report on Form 10-K for the year ended December 31, 2005. The following notes should be read in conjunction with such policies and other disclosures in the Form 10-K. Interim results are not necessarily indicative of results for a full year.

In the opinion of management, the accompanying unaudited interim financial statements contain all material adjustments (consisting of normal, recurring accruals) necessary to fairly present the Company s financial position as of September 30, 2006, the results of the Company s operations for the three and nine months ended September 30, 2006 and 2005, and the Company s cash flows for the nine months ended September 30, 2006 and 2005.

Reclassifications

Certain reclassifications have been made to the prior period s financial information to conform to the September 30, 2006 presentation.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Use of Accounting Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with a maturity of three months or less to be cash and cash equivalents.

Investments Held-to-Maturity

The Company has investments in certain debt securities that have been classified on the balance sheet as investments held-to-maturity in accordance with SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Investments held-to-maturity are recorded on the balance sheet at cost. Realized gains and losses on sales of investments are determined using the specific identification method.

Allowances for Accounts Receivable

The Company maintains allowances for accounts receivable, which include an allowance for doubtful accounts related to the estimated losses that may result from the inability of its customers to make required payments. This allowance is determined based upon historical experience and any specific customer collection issues that have been identified. The Company began selling its first product on November 8, 2004 and has not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Also included in the allowances for accounts receivable is an allowance for early payment discounts.

Inventory

The Company values its inventory at the lower of cost (determined by the first-in, first-out method) or market. The Company regularly reviews inventory quantities on hand and records a provision for excess and obsolete inventory based primarily on estimated forecasts of product demand and production requirements. The Company s estimate of future product demand may prove to be inaccurate, in which case it may have understated or overstated the provision required for excess and obsolete inventory. In the future, if the Company s inventory is determined to be overvalued, the Company would be required to recognize such costs in costs of product sales at the time of such determination. Likewise, if the inventory is determined to be undervalued, the Company may have recognized excess cost of product sales in previous periods and would be required to recognize such additional operating income at the time of sale.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs an Amendment of ARB No. 43, Chapter 4. The standard requires abnormal amounts of idle facility and related expenses to be recognized as current period charges and also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company adopted SFAS No 151 on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on the Company s financial statements.

Property, Plant and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements and capitalized leases are recorded at the fair market value at the inception of the leases and are amortized over the shorter period of their estimated useful life or the lease ranging from five to ten years. Amortization of assets recorded under capital leases is included in depreciation and amortization expense.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Deferred Offering and Financing Costs

Costs incurred in relation to the Company s initial public offering were deferred at December 31, 2005 and have been subsequently netted against gross proceeds raised from the initial public offering of the Company s common stock, which closed on February 7, 2006. Costs incurred in relation to the Company s line of credit were deferred and are being amortized over the two-year term of the loan and are included in other non current assets.

Investment Spepharm

On July 17, 2006, the Company entered into an Investment and Shareholders Agreement in which the Company received a 19.9% ownership interest in a newly created Dutch company called Spepharm Holding B.V. (Spepharm) for a nominal amount of approximately $5,000. Spepharm and its European specialty pharmaceutical group of companies are focusing on becoming one of the leading suppliers of specialty urology and endocrinology products to the European market place. The investment is included in other non current assets.

Net Product Sales

Net product sales are presented net of estimated returns and price adjustments, early payment discounts, group purchasing fees and credit card fees.

Revenue Recognition

The Company s revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition in Financial Statements (SAB 104), and SFAS No. 48, Revenue Recognition When Right of Return Exists (SFAS 48), which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SFAS 48 and SAB 104 require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and the Company s revenue could be adversely affected.

Allowances have been recorded for any potential returns or adjustments in accordance with the Company s policy. Returns are allowed for damaged or outdated goods. As of September 30, 2006, the Company had a reserve of approximately $214,000 for returns and adjustments, all of which related to sales made in 2006. As of September 30, 2006 and at December 31, 2005, there was approximately $20,000 and $300,000 of retail value of Vantas, respectively, at distributors.

	Distributors	Physicians	Total
		(In thousands)	
For the nine months ended September 30, 2006			
Allowance balance at December 31, 2005	$ 19	$ 320	$ 339
Provision related to sales for Fiscal 2006	15	954	969
Returns and adjustments related sales in Fiscal 2004		(50)	(50)
Returns and adjustments related sales in Fiscal 2005	(1)	(325)	(326)
Returns and adjustments related sales in Fiscal 2006	(11)	(707)	(718)
Allowance balance at September 30, 2006	$ 22	$ 192	$ 214

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

For the nine months ended September 30, 2005	Distributors	Physicians (In thousands)	Total
Allowance balance at December 31, 2004	$ 28	$ 316	$ 344
Provision related to sales for Fiscal 2005		1,784	1,784
Returns and adjustments related sales in Fiscal 2004		(288)	(288)
Returns and adjustments related sales in Fiscal 2005	(4)	(1,089)	(1,093)
Allowance balance at September 30, 2005	$ 24	$ 723	$ 747

Customer Sales Urologists

The Company s revenue from product sales is recognized when there is persuasive evidence an arrangement exists, the price is fixed in accordance with the Company s Customer Price List and/or approved exception pricing, or determinable from executed contracts, delivery to the customer has occurred and collectibility is reasonably assured. The Company uses contracts, purchase orders, sales orders directly taken by product specialists and sales order confirmations to determine the existence of an arrangement. Title to the product is taken upon delivery of the product, at which time risk of loss shifts to the customer. Billing does not take place until the day after shipment has occurred. The Company uses shipping documents and is provided with third party proof of delivery to verify delivery to its customers.

Customer Sales Distributors Sales

With respect to sales to distributors, revenue is recognized upon shipment, as the title, risks and rewards of ownership of the products pass to the distributors and the selling price of the Company s product is fixed and determinable at that point, as long as the Company believes the product will be sold by the distributor within one to three months from the shipment of the product by the Company to the distributor. If the Company believes the product will not be resold within three months, revenue will be deferred until the product is sold and the product held by the distributor will be classified as an asset on the Company s financial statements until it is sold by the distributor. As of September 30, 2006 and at December 31, 2005, the Company deferred approximately $0 and $329,000 of revenue and recorded $0 and $44,000 of inventory on consignment, respectively, The 2005 amounts related to product sold to distributors in the fourth quarter of 2005 that were not resold by distributors in accordance with the Company s policy. Payment is due based upon the terms of the contract. The distributor is responsible for selling and distributing the product to its customer base and the rights for return are restricted to the Company s published return policy in effect for all customers.

Royalties

Licensing revenue from royalty arrangements are recorded on a cash basis due to the uncertainties regarding calculations, timing and collections. Royalty expense is recorded as the corresponding revenue is recognized. Royalty expense is included in cost of product sales in the statement of operations.

Shipping and Handling Costs

Shipping and handling costs incurred for inventory purchases and product shipments are included within cost of product sales in the statements of operations.

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research for the Company.

Pre-clinical Study and Clinical Trial Expenses

Research and development expenditures are charged to operations as incurred. The Company s expenses related to clinical trials are based on actual and estimates of the services received and efforts expended pursuant to contracts

with multiple research institutions and clinical research organizations that conduct and manage clinical trials on the Company s behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, the Company modifies its estimates accordingly on a prospective basis.

Advertising Costs

The Company charges advertising costs to selling and marketing expense as incurred.

Intangible Assets

On March 31, 2006, the Company completed its acquisition of the product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada. As of September 30, 2006, the Company has an intangible asset of approximately $473,000 associated with such product rights. The intangible asset was recorded at its original cost of $525,000, less accumulated amortization of approximately $52,000. Intangible assets are stated at cost, less accumulated amortization, and are amortized over their estimated useful lives using the straight-line method. The Company estimates that the useful life of the Valstar product rights is 5 years. The Company periodically reviews the original estimated useful lives of long-lived assets and makes adjustments when appropriate.

Stock-Based Compensation

The Company adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options the Company granted in prior years as a non-public company (prior to the initial filing of its Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. The Company adopted the prospective transition method for these options. Options granted as a public company will be expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how the Company accounts for options issued to non employees. The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

Deferred Compensation

At December, 31 2005, the Company had deferred compensation of approximately $630,000. In accordance with the adoption of FAS 123(R), all deferred compensation related to employee stock options has been eliminated. As of September 30, 2006, the deferred compensation balance was $0.

Income Taxes

The Company utilizes the asset and liability method specified by Statement of Financial Accounting Standards No. 109 (FAS 109), *Accounting for Income Taxes* . Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Long-lived Assets

The Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through September 30, 2006.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Concentration Risks

The financial instrument that potentially subjects the Company to concentration of credit risk is cash. The Company places its cash with high-credit quality financial institutions. Concentrations of credit risk, with respect to this financial instrument, exist to the extent of amounts presented in the financial statements.

The Company generated all of its product sales for the nine months ended September 30, 2006 and 2005 from its product Vantas. In addition, for the three months ended September 30, 2006 and 2005, one customer accounted for 2.4% and 11.4%, respectively of the Company s net unit sales. The same customer accounted for 6.0% and 7.8% respectively, of the Company s net unit sales for the nine months ended September 30, 2006 and 2005 and 0% of its outstanding receivables as of September 30, 2006 and at December 31, 2005, respectively.

The Company is dependent on single suppliers for certain raw materials, including histrelin, the active pharmaceutical ingredient in Vantas. The Company does not have an agreement with the supplier of histrelin.

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair values.

Recent Accounting Pronouncements

In July 2006, the FASB issued FIN 48 *Accounting for Uncertainty in Income Taxes* which clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes.* FIN 48 requires an entity to recognize the benefit of tax positions only when it is more likely than not, based on the position s technical merits, that the position would be sustained upon examination by the respective taxing authorities. The tax benefit is measured as the largest benefit that is more than fifty-percent likely of being realized upon final settlement with the respective taxing authorities. FIN 48 is effective for fiscal years beginning after December 15, 2006. FIN 48 is not expected to have a material effect on the results of operations or financial position of the Company.

In September 2006, the FASB issued Statement of Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measurements but eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the company has not yet issued financial statements, including for interim periods, for that fiscal year. The Company is evaluating the impact of SFAS 157, but does not expect the adoption of SFAS 157 to have a material impact on the Company s financial position, results of operations or cash flows.

Note 3. Investments

The Company has investments in certain debt securities that have been classified on the balance sheet as investments held-to-maturity in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Investments held-to-maturity have been recorded on the balance sheet at cost. Realized gains and losses on sales of investments are determined using the specific identification method. In August 2006, one U.S. government and agency security matured and was sold by the Company for $3,000,000. No realized gains or losses were recognized on the transaction. The Company did not have any investments as of December 31, 2005.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

The amortized cost, gross unrecognized gains and losses, and fair value of the Company s held-to-maturity investments are summarized as follows:

	September 30, 2006 Held-to-Maturity (in thousands)			
Description of Securities	Amortized Cost	Gross Unrecognized Gains	Gross Unrecognized Losses	Fair Value
U.S. government and agencies securities	$2,982	$ 2	$	$2,984

The fair value of the Company s held to maturity securities as of September 30, 2006, by contractual maturity, is shown below. Expected maturities may differ from contract maturities because borrowers may have the right to prepay and creditors may have the right to call certain obligations.

	September 30, 2006 Held-to-Maturity (in thousands)	
Maturity	Amortized Cost	Fair Value
Due in one year or less	$ 2,982	$ 2,984
Due after one year through five years		
Due after five years through ten years		
Due after ten years		
	$ 2,982	$ 2,984

Note 4. Inventory

Inventories consist of the following:

	September 30, 2006 (unaudited)	December 31, 2005
	(in thousands)	
Raw materials	$ 870	$ 463
Work-in-process	4,004	2,426
Finished goods	695	302
	$ 5,569	$ 3,191

The preceding amounts are net of inventory reserves of approximately $1.1 million and $1.2 million as of September 30, 2006 and at December 31, 2005, respectively, for certain raw materials and for certain products that failed to meet the Company s quality control specifications.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Note 5. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	Useful Lives	September 30, 2006 (unaudited)	December 31, 2005
		(in thousands)	
Laboratory equipment	5 years	$ 1,794	$ 1,531
Furniture and Fixtures	7 years	185	161
Office equipment	5 years	136	108
Computer equipment	3 years	481	417
Computer software	3 years	301	200
Construction in process		5,650	2,526
Leasehold improvements	1-10 years	754	625
		9,301	5,568
Less accumulated depreciation and amortization		(1,788)	(1,374)
Property, plant and equipment, net		$ 7,513	$ 4,194

Depreciation expense and amortization for the three months ended September 30, 2006 and 2005 was approximately $148,000 and $153,000, respectively. Depreciation expense and amortization for the nine months ended September 30, 2006 and 2005 was approximately $414,000 and $352,000, respectively. There were property, plant and equipment assets totaling approximately $96,000 as of September 30, 2006 and $68,000 at December 31, 2005, respectively, subject to capital lease obligations with accumulated amortization of approximately $66,000 and $54,000 as of September 30, 2006 and at December 31, 2005, respectively.

The Company is currently in the process of expanding its manufacturing facilities in order to support current and future product candidates. The costs related to the expansion are captured in the table above as Construction in process . The expansion is expected to be completed in the fourth quarter of 2006.

Note 6. Deferred Offering and Financing Costs

The Company had deferred offering costs of $0 and approximately $1.4 million as of September 30, 2006 and at December 31, 2005, respectively. The Company netted its deferred offering costs against the gross proceeds raised from the initial public offering which closed on February 7, 2006. In connection with the Company s line of credit, the Company had deferred financing costs of approximately $73,000 and $124,000 as of September 30, 2006 and at December 31, 2005, respectively. Deferred financing costs are being amortized through interest expense over the two year term of the loan and are included in other non current assets.

Note 7. Credit Line Agreement (Note Payable)

In October 2005, the Company entered into a two-year, $7,500,000 line of credit with Merrill Lynch Capital. Under the line of credit, the amount the Company may borrow at any given time is dependent upon its accounts receivable balance and related aging of such accounts. In June 2006, the line of credit was amended for interest, covenant and operational terms. Borrowings under the amended line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.25% (8.57% as of September 30, 2006). The Company is subject to certain covenants under the amended line of credit. In connection with the amended line of credit, the Company pledged all of its assets, with the exception of intellectual property, to Merrill Lynch. As of September 30, 2006 and at December 31, 2005, the Company had $0 and approximately $1.5 million outstanding under the amended line of credit, respectively.

In February 2006, the Company used a portion of the net proceeds from its initial public offering to repay amounts outstanding under the line of credit.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Note 8. Capitalization

Common Stock

The Company had 14,934,807 and 1,667,082 shares of common stock, par value $0.001, outstanding as of September 30, 2006 and at December 31, 2005, respectively. The Company is authorized to issue 30,000,000 shares of common stock with a par value of $0.001 per share. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

In February 2006, the Company closed its IPO in which it issued 3,862,500 shares of its common stock at $9.00 per share. In conjunction with this offering all of the Company s outstanding preferred stock converted into 9,355,714 shares of common stock. As a result, the Company had 14,885,296 shares of common stock outstanding after closing its initial public offering. During the nine months ended September 30, 2006, 49,511 shares of common stock were issued as a result of stock option exercises.

Convertible Preferred Stock

All of the Company s outstanding preferred stock was converted into common stock in conjunction with the initial public offering. In February 2006, the Company filed an amended and restated Certificate of Incorporation that removed the designations, rights and preferences of the convertible preferred stock.

Note 9. Stock-Based Compensation

The Company adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options the Company granted in prior years as a non-public company (prior to the initial filing of its Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. The Company adopted the prospective transition method for these options. Options granted as a public company will be expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how the Company accounts for options issued to non employees. The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

Under the modified-prospective-transition method, under SFAS No. 123(R), the Company is required to record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding as of the beginning of the period of adoption. The Company measured stock-based compensation using the Black Scholes option pricing model.

The following ranges of assumptions were used to compute employee stock-based compensation:

Risk- free interest rate	3.90% - 5.01%
Expected volatility	61.1% - 66.15%
Expected dividend yield	0.0%
Expected life (in years)	6.25
Forfeiture rate	0% - 4.0%
Weighted average fair value at date of grant	$ 6.20

Expected volatility is based upon an appropriate peer group within the Company s industry sector. The expected life of the awards represents the period of time that options granted are expected to be outstanding.

The Company used historical information to estimate forfeitures within the valuation model. The risk-free rate for periods within the expected life of the option is based on implied yields on U.S. Government Issues in effect at the time of grant. Compensation cost is recognized using a straight-line method over the vesting or service period and net of estimated forfeitures.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

The following table presents all employee stock based compensation costs recognized in the Company s statements of operations:

	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2006	2005	2006	2005
Employee stock-based compensation under intrinsic value method	$ 42	$ 127	$ 151	$ (56)
Employee stock-based compensation under fair value method	261		576	
Total Employee stock-based compensation	$ 303	$ 127	$ 727	$ (56)

In 2005, as a result of the Company s marked to market of previous repriced options, the Company had to reverse previous recorded stock-based compensation.

The incremental stock-based compensation expense recognized in connection with the adoption of FAS 123(R) increased the net loss for the three and nine month periods ended September 30, 2006, by approximately $261,000 and $576,000, respectively, and increased the loss per share, basic and diluted, $(0.02), and $(0.04), respectively.

The following table illustrates the pro-forma effect on net income per share if the Company recorded compensation expense based on the fair value method for all employee stock-based compensation awards:

	Three Months Ended September 30, 2005 (in thousands, except per share amounts)	Nine Months Ended September 30, 2005 (in thousands, except per share amounts)
Net income to common stock holders as reported	$ (2,808)	$ 151
Add: non-cash employee compensation as reported	127	(56)
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(218)	(527)
Net income to common stockholders pro-forma	$ (2,899)	$ (432)
Basic income per share as reported	$ (1.68)	$ 0.09
Basic income per share pro-forma	$ (1.74)	$ (0.26)
Diluted income per share as reported	$ (1.68)	$ 0.01
Diluted income per share pro-forma	$ (1.74)	$ (0.26)

The following table is a summary of stock option activity under the Company s Equity Incentive Plan (the Plan) for the Company s common stock at December 31, 2005, and changes during the nine months ended September 30, 2006:

	Common Stock	Weighted Average Exercise	Aggregate	Weighted Average Contractual

	Options	Price	Intrinsic Value (in thousands)	Life
Outstanding at December 31, 2005	1,265,849	$ 4.25		
Granted	350,200	$ 9.00		
Exercised	(49,511)	$ 3.05		
Forfeited	(101,784)	$ 6.63		
Outstanding at September 30, 2006	1,464,754	$ 5.26	$ 611	7.8
Exercisable at September 30, 2006	617,146	$ 3.59	$ 155	7.2

The total intrinsic value of the options exercised during the nine months ended September 30, 2006 was $123,729. As of September 30, 2006, there was approximately $2.7 million of total employee unrecognized compensation cost related to non-vested stock-based compensation awards granted under the Plan. That cost is expected to be recognized over a weighted average period of three years.

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

For the nine months ended September 30, 2006 and 2005, the Company granted a total of 0 and 10,833 options, respectively, to certain consultants. The Company has accounted for non-employee options in accordance with EITF 96-18 and, accordingly, recorded non-cash (income) expense of approximately $(6,000) and $14,000 for the three months ended September 30, 2006 and 2005, respectively. The Company recorded a non-cash (income) expense of approximately $(1,000) and $72,000 for the nine months ended September 30, 2006 and 2005, respectively.

For the three months ended September 30, 2006 and 2005, the company granted stock options with exercise prices as follows:

Grants Made During Quarter Ended	Number of Options Granted	Weighted Average Exercise Price	Weighted Average Fair Value per Share	Weighted Average Intrinsic Value per Share
September 30, 2006	7,500	$ 7.36	$ 4.79	
September 30, 2005	4,334	$ 12.00	$ 12.00	

Note 10. Income Taxes

The benefit for federal, state and local income taxes for the three months ended September 30, 2006 and 2005 was $36,000 and $300,000, respectively. The benefit for federal, state and local income taxes for the nine months ended September 30, 2006 and 2005 was $16,000 and $0, respectively. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amount used for income tax purposes. The Company s net deferred tax assets relate primarily to net operating loss carry forwards, research and development tax credits, non-cash stock-based compensation, and depreciation and amortization. As of September 30, 2006 and at December 31, 2005, a valuation allowance was recorded to fully offset the net deferred tax asset.

Note 11. Net Income (Loss) Per Share

The Company computes its basic net income (loss) per share by dividing net income (loss) by the weighted-average number of shares of common stock outstanding. Diluted net income (loss) per share of common stock (Diluted EPS) is computed by dividing net income (loss) by the weighted-average number of shares of common stock and dilutive common equivalent shares then outstanding as long as such impact would not be anti-dilutive. All of the common stock equivalent shares for the three and nine months ended September 30, 2006 have been excluded from the computation of diluted net income (loss) per share as their effect would be anti-dilutive. All of the common stock equivalent shares for the three months ended September 30, 2005 have been excluded from the computation of diluted net income (loss) per share as their effect would be anti-dilutive.

	Three Months Ended September 30,			
	2006		2005	
	Net (loss) (Numerator)	Shares (Denominator)	Net (loss) (Numerator)	Shares (Denominator)
	(in thousands, except per share amounts)			
Basic net (loss) per share factors	$ (4,684)	14,906	$ (2,808)	1,667
Effect of preferred stock conversion				
Effect of dilutive stock options				

Diluted net (loss) per share factors	$ (4,684)	14,906	$ (2,808)	1,667
Basic net (loss) per share	$ (0.31)		$ (1.68)	
Diluted net (loss) per share	$ (0.31)		$ (1.68)	

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VALERA PHARMACEUTICALS, INC
NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

	Nine Months Ended September 30,			
	2006		2005	
	Net (loss) (Numerator)	Shares (Denominator)	Net income (Numerator)	Shares (Denominator)
	(in thousands, except per share amounts)			
Basic net (loss) income per share factors	$ (9,538)	13,123	$ 151	1,667
Effect of preferred stock conversion				8,834
Effect of dilutive stock options				857
Diluted net (loss) income per share factors	$ (9,538)	13,123	$ 151	11,358
Basic net (loss) income per share	$ (0.73)		$ 0.09	
Diluted net (loss) income per share	$ (0.73)		$ 0.01	

Note 12. Related Party Transactions

Sanders Morris Harris Inc. (SMH) and its affiliates own approximately 40% of BioPro Pharmaceutical, Inc. and over 90% of Alpex Pharma S.A., two companies with which the Company has agreements to distribute, develop and market its Vantas product. The Company received payments of $100,000 and $0 during the three months ended September 30, 2006 and 2005, respectively, from BioPro. The Company received payments of $100,000 and $300,000 during the nine months ended September 30, 2006 and 2005, respectively, from BioPro. The Company made payments of $84,000 and $241,000 during the three months ended September 30, 2006 and 2005, respectively, to Alpex. The Company made payments of $145,000 and $393,000 during the nine months ended September 30, 2006 and 2005, respectively, to Alpex.

On July 17, 2006, the Company entered into the Shareholders Agreement pursuant to which the Company received a 19.9% ownership in a newly created Dutch company called Spepharm Holding B.V. In accordance with the Shareholders Agreement, David S. Tierney, M.D., Valera s President and Chief Executive Officer and Mr. James Gale, the Company s Chairman of the Board of Directors, were appointed as members of Spepharm s initial supervisory board. Additional investors in Spepharm include Life Sciences Opportunities Fund (Institutional) II, L.P and Life Sciences Opportunities Fund II, L.P. Both funds are funds managed by, and affiliates of, SMH, whose affiliates own approximately 36% of the outstanding common stock of the Company. Mr. Gale is a Managing Director of SMH and the investment manager of such funds that hold shares of Valera and has sole voting and dispositive power over such shares. SMH, along with a third party unaffiliated with the Company, have committed EUR 20,000,000 to the Spepharm venture. As discussed in Note 1 to these Financial Statements, on September 27, 2006, the Company entered into a License and Distribution Agreement with Spepharm.

Note 13. Acquisition of Product

In March 2006, the Company completed the acquisition of certain assets of Anthra Pharmaceuticals associated with its valrubicin business in the United States and Canada. The Company will make: (i) installment payments totaling approximately $0.5 million; (ii) additional payments of up to 13.5% of net sales depending upon the product s formulation, indication and market share; and (iii) certain milestone payments based upon achieving certain sales levels. Anthra s valrubicin business involved the manufacture and sale of valrubicin for use in the treatment of bladder cancer. The product was distributed in the U.S. and Canada by third party partners of Anthra. In the United States, the product was distributed under the trademark Valstar. Product rights are stated at cost, less accumulated amortization, and are amortized over their estimated useful lives using the straight-line method. The Company estimates that the

useful life of the Valstar product rights is 5 years. For the three and nine months ended September 30, 2006, the Company recorded approximately $26,000 and $52,000, respectively, of amortization expense associated with such product rights. The Company periodically reviews the original estimated useful lives of long-lived assets and makes adjustments when appropriate. There were no such adjustments made as of September 30, 2006.

Note 14. Purchase Commitments

On May 17, 2006, the Company entered into a supply agreement with Plantex USA Inc. whereby Plantex would supply the Company with the active pharmaceutical ingredient (API) N-Trifluroacetyl-adriamycin-14 valerate, otherwise known as Valrubicin,

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in connection with the Company s anticipated launch of the product Valstar for the treatment of bladder cancer. Under the agreement, the Company will only source API from Plantex in connection with the development, manufacture or sale of, and securing regulatory approval for, Valstar in the United States, its territories and possessions, and Canada (the Territory). Plantex will manufacture and supply all of the Company s requirements for API for commercial sale of Valstar in the Territory. Under the terms of the agreement, beginning in the calendar year following the year in which the Company receives regulatory approval for the Valstar product in the United States, the Company will be required to purchase a minimum of $1,000,000 of Valrubicin each calendar year until the agreement expires. The agreement will expire ten years after the date of the first commercial sale of Valstar.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Introduction

The following information should be read in conjunction with the financial statements and related notes in Part I, Item 1 of this Quarterly Report and with Management s Discussion and Analysis of Financial Condition and Results of Operations contained in the our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. In addition to historical information, this Form 10-Q contains forward-looking information. This forward-looking information is subject to certain risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Important factors that might cause such a difference include, but are not limited to, those discussed in the following section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis only as of the date of this Form 10-Q. We undertake no obligation to publicly revise or update these forward-looking statements to reflect events or circumstances which arise later. Readers should carefully review the risk factors described in our Annual Report on Form 10-K filed with the SEC, as modified in our Quarterly Report on Form 10-Q filed with the SEC on August 9, 2006.

Overview

We are a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize our proprietary technology. Our first product, Vantas, was approved by the FDA in October 2004. Vantas is a 12-month hydrogel implant based on our patented Hydron Technology indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, a luetinizing hormone-releasing hormone agonist, or LHRH agonist. We began selling Vantas in November 2004 utilizing our sales force that is currently calling on urologists in the United States that account for the majority of LHRH agonist product sales. Total U.S. sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately $900 million in 2005 based on our estimates and IMS Health Incorporated data, with the leading products being the three and four-month injection formulations. We believe that total U.S. sales of LHRH agonist products declined by 10% in 2005, primarily as a result of lower prices due to changes in Medicare reimbursement rates. We expect future reimbursement levels to continue to decline, which will have an adverse effect on our net product sales. We believe that Vantas has a competitive advantage over other LHRH agonist products because it delivers an even, controlled dose of a LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available.

We plan to seek marketing approvals for Vantas in various countries throughout the world. In November 2005, we announced that we received approval to market Vantas in Denmark. In March 2006, we announced that Paladin Labs received approval from Health Canada to market our Vantas product in Canada. In July 2006, we submitted an application for regulatory approval in Germany, Ireland, Italy, Spain and the United Kingdom. In July 2006, we announced a partnership with Spepharm to market Vantas in Denmark and throughout Europe. As of September 30, 2006, in conjunction with one of our marketing partners, Vantas has been submitted for regulatory approval in Thailand, Singapore, Malaysia, Taiwan, Korea and Hong Kong.

In June 2006, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for Supprelin-LA, a twelve-month implant for the treatment of central precocious puberty. In September 2006, the FDA accepted our submission of our NDA for Supprelin-LA. Accordingly, under the Prescription Drug User Fee Act

(PDUFA) guidelines, the FDA is expected to complete its review and act upon this NDA submission by the PDUFA required date of May 3, 2007.

In March 2006, we acquired Valstar a product for the treatment of bladder cancer that is no longer responsive to conventional treatment such as surgery or topical drug application. We expect to launch this product in the first quarter of 2007. In addition to Supprelin-LA, Valstar and Vantas, we are developing a pipeline of proprietary product candidates for indications that include acromegaly, opioid addiction, interstitial cystitis and nocturnal enuresis. Several of our product candidates also utilize our Hydron

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Technology delivery system. We intend to leverage our existing specialized sales force to market certain of our product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians we are calling on for Vantas.

We expect to continue to spend significant amounts on the development and commercialization of our product candidates. While we will be focusing on the clinical development of our later stage product candidates in the near term, we expect to increase our spending on earlier stage clinical candidates as well. We also aim to build our urological and endocrine product portfolio and opportunistically acquire or in-license later-stage urological and endocrine products that are currently on the market or require minimal development expenditures, or have some patent protection or potential for market exclusivity or product differentiation. Further, we intend to collaborate with major and specialty pharmaceutical companies to develop and commercialize products that are outside of our core urology and endocrinology focus. Accordingly, we will need to generate significant revenues or else need additional financing to fund these efforts.

Drug development in the United States and most countries throughout the world is a multi-stage process controlled by the FDA and similar regulatory authorities in foreign countries. In the United States, the FDA approval process for a new drug involves completion of pre-clinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an investigational new drug application, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant expenses associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development stage. In responding to a new drug application, the FDA may refuse to accept the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In order to commence clinical trials or marketing of a product outside the United States, we must obtain approval of the applicable foreign regulatory authorities. Although governed by the laws and regulations of the applicable country, clinical trials conducted outside the United States typically are administered in a similar three-phase sequential process.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- future clinical trial results;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Research and development expenses consist primarily of costs incurred for clinical trials and manufacturing development costs related to our clinical product candidates, personnel and related costs related to our research and

product development activities and outside professional fees related to clinical development and regulatory matters. We do not disclose estimated research and development costs for product candidates that are not yet in Phase III clinical trials.

Recent Events

On September 7, 2006, we announced that the FDA had accepted the submission of our NDA for Supprelin®-LA, a 12-month implant for treating central precocious puberty (CPP) or the early onset of puberty in children. Accordingly, under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to complete its review and act upon this NDA submission by the PDUFA required date of May 3, 2007. In November 2005, the FDA granted Supprelin®-LA orphan drug designation which provides seven years marketing exclusivity from date of marketing approval as well as certain economic benefits and tax credits. We also announced that our Supprelin-LA manufacturing facilities in Cranbury, New Jersey successfully passed a recent FDA pre-approval inspection.

On September 27, 2006, we entered into a License and Distribution Agreement with Spepharm Holding B.V. (Spepharm). Under the terms of the agreement, we will give Spepharm the exclusive licensing and distributing rights to our products under the trademark Vantas® and Supprelin® in the European Union as well as Norway and Switzerland for a period of ten years, unless sooner terminated as provided by the agreement. Spepharm will pay us for our supply and Spepharm s distribution of the products under the

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agreement an aggregate amount equal to forty percent (40%) of Net Sales (the Royalty Amount) as defined by the agreement based on an established transfer price. In addition, following the end of each quarter, Spepharm will pay us an amount equal to the difference between (a) the aggregate Royalty Amount for such calendar quarter minus (b) the aggregate transfer prices paid by Spepharm during such calendar quarter.

On November 6, 2006, we announced that we finalized arrangements with Johns Hopkins to begin clinical studies for our Naltrexone implant. This is a subcutaneous implant that utilizes our Hydron technology to deliver Naltrexone, over an extended period of time, for the treatment of opioid addiction.

On November 8, 2006, we announced that we completed proof-of-concept studies on a flexible, biodegradable polymer-based ureteral stent. Ureteral stents are plastic tubes inserted into the ureter to allow urine to drain from the kidney to the bladder when the flow of urine may be obstructed due to a number of conditions, including kidney stones and inflammation. Current available ureteral stents require physician intervention for removal from the body. A biodegradable ureteral stent could be naturally voided by the body, a potentially important advantage over existing stents. We expect to move this program into larger porcine model studies during the fourth quarter which, if successful, could lead to a 510K filing with the FDA in 2007.

Product Sales and Costs

We generate revenues from sales of Vantas, our lead product. We began commercial sales of Vantas in November 2004. Prior to June 2006, all sales were in the United States. In June 2006, we made our first international shipment of Vantas to Paladin Labs in Canada. In the United States, we distribute Vantas directly to physicians, or through Besse Medical Distribution Company, or Besse Medical, which is a subsidiary of AmerisourceBergen Corporation.

Our business is affected by physician utilization, pricing pressure from our competition and Medicare or third party reimbursement, as well as other factors which may cause variances in our revenue. Our sales of Vantas from launch in November 2004 through June 30, 2005 were supported, in part, by favorable reimbursement rates, which decreased beginning in the third quarter of 2005. Our initial favorable reimbursement rates were due to the fact that Vantas was a new product that did not yet have an established average selling price or ASP, in connection with Medicare reimbursement. As a result, Vantas was reimbursed at wholesale acquisition price, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which resulted in lower reimbursement rates and a corresponding lower sales price to our customers. Our historical net average selling prices to our customers are:

For the three months ended:	Net Average Selling Price
December 31, 2004	$ 2,520
March 31, 2005	$ 2,628
June 30, 2005	$ 2,586
September 30, 2005	$ 2,099
December 31, 2005	$ 1,801
March 31, 2006	$ 1,620
June 30, 2006	$ 1,562
September 30, 2006	$ 1,478

We expect future Medicare reimbursement levels to continue to decline for Vantas, which will have an adverse effect on our net product sales. Reimbursement levels are currently set by the twenty-three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on our ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which

segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, sometimes referred to as a split policy. Finally, there are certain Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which we believe make payments based upon a split policy.

We are devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, we are at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. We are challenging the basis for these reimbursement policies with the Medicare carriers. We will deploy our sales resources in markets where we can sell our products on an even par with the other products in the class. Nevertheless, we expect our net product sales to continue to decline in the foreseeable future as a result of the declining reimbursement rates for Vantas.

We are also pursuing a sales strategy in which we will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on our net average selling price from the Medicare customers. In addition, we are currently reviewing a number of strategic options to broaden the penetration of Vantas into the LHRH market, including the evaluation of co-promotion opportunities.

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Our cost of product sales are all related to the production of Vantas and represent the cost of materials, overhead associated with the manufacture of Vantas, direct labor, distribution charges and royalties. For a complete description of our royalty agreements please review our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. Prior to approval of Vantas in October 2004, we expensed all of our manufacturing costs as research and development.

Research and Development Expenses

Our research and development expenses consist of costs incurred for company-sponsored and collaborative research and development activities including clinical trials. These expenses consist primarily of direct and research related allocated overhead expenses such as facilities costs, salaries and benefits and material supply costs. We do not track or report our research and development expenses on a project basis as we do not have the internal resources or systems to do so. To date, the vast majority of our research and development resources have been devoted to the development of Vantas.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of sales and marketing personnel compensation, sales force incentive compensation, travel, tradeshows, promotional materials and programs, advertising and healthcare provider education materials and events.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel expenses for accounting, human resources, outside consulting, information technology and corporate administration functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal and accounting services.

Amortization of Intangible Assets

The amortization of intangible assets relates to the acquisition of the product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada. The Company is amortizing the product rights over 5 years using the straight-line method.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, the expected course of development, historical experience and other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. The list below is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management s judgment in selecting any available alternative would not produce a materially different result.

Revenue Recognition

Our revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition in Financial Statements (SAB 104), and SFAS No. 48, Revenue Recognition When Right of Return Exists (SFAS 48), which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SFAS 48 and SAB 104 require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and our revenue

could be adversely affected.

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Allowances have been recorded for any potential returns or adjustments in accordance with our policies. We historically have recorded allowances based upon a percentage of gross sales. We distribute our product directly to physicians or through our distributor, Besse Medical. The majority of our sales are made directly to physicians by our product specialists. We believe that physicians typically order product on an as needed basis, and, therefore, typically maintain inventory of our product only to cover their immediate and short-term future requirements. In addition, our product specialists routinely confirm product utilization and inventory levels, if any, as part of their normal sales calls with physicians. We continue to monitor our distribution channels in order to assess the adequacy of our allowances. We do not believe that it is reasonably likely that a material change will occur in the allowance as of September 30, 2006.

Pre-clinical Study and Clinical Trial Expenses

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on actual and estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

Stock-Based Compensation

We adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options we granted in prior years as a non-public company (prior to the initial filing of our Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. We adopted the prospective transition method for these options. Options granted as a public company will be expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how we account for options issued to non employees. We account for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

Results of Operations

Three months ended September 30, 2006 compared with three months ended September 30, 2005

Net Product Sales. Net product sales for the three months ended September 30, 2006 and 2005 were approximately $2.9 and $3.7 million, respectively. The 21% decrease in net product sales was primarily due to lower net average selling prices due to decreased Medicare reimbursement rates for our Vantas product as well as increased competitive pricing in the class of LHRH drugs. For the three months ended September 30, 2006, we sold 1,968 units of Vantas in the United States at a net average selling price of $1,478 per unit as compared to 1,747 units at a net average selling price of $2,099 for the same period in 2005.

Vantas is currently eligible for insurance reimbursement coverage. We expect future Medicare reimbursement levels to continue to decline for Vantas, which will have an adverse effect on our net product sales. Reimbursement levels are currently set by the twenty- three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on our ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of

LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, or a split policy. Finally, there are certain Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which we believe make payments based upon a split policy.

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We are devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, we are at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. We are challenging the basis for these reimbursement policies with the Medicare carriers. We will deploy our sales resources in markets where we can sell our products on an even par with the other products in the class.

We are also pursuing a sales strategy in which we will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on our net average selling price from the Medicare customers. In addition, we are currently reviewing a number of strategic options to broaden the penetration of Vantas into the LHRH market, including the evaluation of co-promotion opportunities.

Licensing Revenue. For the three months ended September 30, 2006 and 2005, we recorded licensing revenues of approximately $104,000 and $10,000, respectively. In September 2006, we received $100,000 from BioPro for licensing revenue related to the submission of Vantas for regulatory approval in Taiwan. This payment is in accordance with the exclusive license and distribution agreement with BioPro to sell Vantas in various countries in Asia. The remaining $4,000 licensing revenue for the three months ended September 30, 2006 was from Hydron Technologies. The entire $10,000 in licensing revenue during the three months ended September 30, 2005 was from Hydron Technologies.

Cost of Product Sales. Our cost of product sales for the three months ended September 30, 2006 and 2005 was approximately $0.9 million and $0.8 million, respectively. Gross margins as a percentage of net product sales for the three months ended September 30, 2006 and 2005 were 70% and 78%, respectively. The decrease in gross margin percentage was primarily due to a decrease in the net average selling prices of Vantas.

Research and Development Expense. Research and development expense for the three months ended September 30, 2006 and 2005, was approximately $1.9 million and $1.5 million, respectively. The 27% increase was primarily due to expenses related to Valstar, Supprelin, Octreotide and European filing fees for Vantas. Expenses related to clinical trials and research projects pursuant to contracts with research institutions and clinical research organizations represented 56% of our total research and development expense for the three months ended September 30, 2006 compared to 50% of our research and development expense for the three months ended September 30, 2005. Internal research and development expense was approximately 44% and 50% of our total research and development expense for the three months ended September 30, 2006 and 2005, respectively. We expect to continue to spend significant amounts, including clinical trial costs, on the development for our product candidates. In August 2006, the FDA requested an additional Phase I/II study for our Octreotide implant which is expected to cost approximately $0.9 million. We expect to commence a Phase III trial for the Octreotide implant in the first half of 2007. The Octreotide Phase III trial is expected to last approximately eighteen months and is expected to cost approximately $6.0 million to $7.0 million.

Selling and Marketing Expense. Selling and marketing expense for the three months ended September 30, 2006 and 2005 was approximately $3.2 million and $2.9 million, respectively. The 10% increase was attributable to an increase in salaries, employee benefits, and travel related to an increase in the number of employees dedicated to our sales efforts.

General Administrative Expense. General administrative expense for the three months ended September 30, 2006 and 2005 was approximately $2.0 million and $1.6 million, respectively. The 25% increase was primarily due to an increase in non-cash stock based compensation expense of approximately $0.2 million, $0.1 million in directors and officer s liability insurance expense, and $0.1 million in rent.

Amortization of Intangible Assets. Amortization expense for the three months ended September 30, 2006 was approximately $26,000. The amortization of intangible assets relates to product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada, which the Company acquired in March of 2006. As such, there was no amortization expense for the three months ended September 30, 2005.

Net Interest Income. Net interest income for the three months ended September 30, 2006 and 2005, was approximately $269,000 and $19,000, respectively. The increase was primarily due to the increased cash and

investments balance resulting from the proceeds of the initial public offering of our common stock in February 2006.

Income Taxes. Income tax benefit for the three months ended September 30, 2006 and 2005 was approximately $36,000 and $300,000, respectively. As a result of the loss of approximately $4.7 million for the three months ended September 30, 2006, as well as the previous net operating losses since our inception, we did not record any federal provision for income taxes during the period ended September 30, 2006. We did record a benefit of $2,000 during the period to adjust for state taxes subject to alternative minimum tax. An additional benefit of $34,000 was recorded as a result of the finalizing and filing of our 2005 federal and state tax

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returns. The $300,000 benefit for taxes at September 30, 2005 was a result of the loss before income taxes of approximately $3.1 million for the three months ended September 30, 2005. Our deferred tax assets primarily consist of net operating loss carry forwards and research and development tax credits. We have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain.

Nine months ended September 30, 2006 compared with nine months ended September 30, 2005

Net Product Sales. Net product sales for the nine months ended September 30, 2006 and 2005 were approximately $14.6 million and $21.6 million, respectively. The 32% decrease in net product sales was primarily due to lower net average selling prices due to decreased Medicare reimbursement rates for our Vantas product as well as increased competition around pricing in the class of LHRH drugs. For the nine months ended September 30, 2006, we sold 9,339 units of Vantas in the United States at a net average selling price of $1,549 per unit as compared to 8,646 units at a net average selling price of $2,502 for the same period in 2005. As a result of our pre-launch shipment of Vantas to Paladin Labs, we sold 115 units of Vantas in Canada. Thus, worldwide unit sales of Vantas increased by 9%, or 808 units, for the nine months ended September 30, 2006, as compared to the same period in the prior year.

Vantas is currently eligible for insurance reimbursement coverage. Sales of Vantas in the nine months ended September 30, 2005 were supported, in part by favorable reimbursement rates, due to the fact Vantas was a new product that did not yet have an established average selling price, or ASP, it was reimbursed at wholesale acquisition price, which is typically higher than ASP. Effective July 2005, Vantas received an established ASP, which resulted in a lower reimbursement rate.

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

We are devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, we are at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. We are challenging the basis for these reimbursement policies with the Medicare carriers. We will deploy our sales resources in markets where we can sell our products on an even par with the other products in the class.

We are also pursuing a sales strategy in which we will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on our net average selling price from the Medicare customers. In addition, we are currently reviewing a number of strategic options to broaden the penetration of Vantas into the LHRH market, including the evaluation of co-promotion opportunities.

Licensing Revenue. For the nine months ended September 30, 2006 and 2005, we recorded licensing revenues of approximately $116,000 and $26,000, respectively. In September 2006, we received $100,000 from BioPro for licensing revenue related to the submission of Vantas for regulatory approval in Taiwan. This payment is in accordance with the exclusive license and distribution agreement with BioPro to sell Vantas in various countries in Asia. The remaining $16,000 licensing revenue during the nine months ended September 30, 2006 was from Hydron Technologies. The entire $26,000 in licensing revenue during the nine months ended September 30, 2005 was from Hydron Technologies.

Cost of Product Sales. Our cost of product sales for the nine months ended September 30, 2006 and 2005 was approximately $4.0 million and $4.8 million, respectively. Gross margins as a percentage of net product sales for the

nine months ended September 30, 2006 and 2005 were 73% and 78%, respectively. The decrease in gross margin percentage was primarily due to a decrease in the net average selling prices which was slightly offset by an inventory reserve charge recorded in prior year. During the nine months ended September 30, 2005, a $1.0 million inventory reserve was recorded for certain products that failed to meet our quality control specifications.

Research and Development Expense. Research and development expense for the nine months ended September 30, 2006 and 2005 was approximately $5.7 million and $4.4 million, respectively. The 30% increase was primarily due to expenses related to Valstar,

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Supprelin, Octreotide and European filing fees for Vantas. Expenses related to clinical trials and research projects pursuant to contracts with research institutions and clinical research organizations represented 48% of our total research and development expense for the nine months ended September 30, 2006 compared to 44% of our research and development expense for the nine months ended June 30, 2005. Internal research and development expense was approximately 52% and 56% of our total research and development expense for the nine months ended September 30, 2006 and 2005, respectively. We expect to continue to spend significant amounts, including clinical trial costs, on the development for our product candidates. In August 2006, the FDA requested an additional Phase I/II study for our Octreotide implant which is expected to cost approximately $0.9 million. We expect to commence a Phase III trial for the Octreotide implant in the first half of 2007. The Octreotide Phase III trial is expected to last approximately eighteen months and is expected to cost approximately $6.0 million to $7.0 million.

Selling and Marketing Expense. Selling and marketing expense for the nine months ended September 30, 2006 and 2005 was approximately $9.7 million and $8.2 million, respectively. The 18% increase was attributable to an increase in salaries, employee benefits, and travel related to an increase in the number of employees dedicated to our sales efforts.

General Administrative Expense. General administrative expense for the nine months ended September 30, 2006 and 2005 was approximately $5.6 million and $4.1 million, respectively. The 37% increase was primarily due to an increase in non-cash stock based compensation expense of approximately $0.6 million, $0.3 million in directors and officer s liability insurance expense, $0.2 million in rent, $0.2 million in professional service fees and $0.2 in director fees.

Amortization of Intangible Assets. Amortization expense for the nine months ended September 30, 2006 was approximately $52,000. The amortization of intangible assets relates to product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada, which the Company acquired in March of 2006. As such, there was no amortization expense for the nine months ended September 30, 2005.

Net Interest Income. Net interest income was approximately $747,000 and $46,000 for the nine months ended September 30, 2006 and 2005, respectively. The increase was primarily due to the increased cash and investments balance resulting from the proceeds of the initial public offering of our common stock in February 2006.

Income Taxes. Income tax benefit for the nine months ended September 30, 2006 and 2005 was approximately $16,000 and $0, respectively. As a result of the loss of approximately $9.6 million for the nine months ended September 30, 2006, as well as the previous net operating losses since our inception, we did not record any federal provision for income taxes during the period ended September 30, 2006. We did record a provision of $18,000 during the period for state taxes subject to alternative minimum tax. The provision was offset by approximately $34,000 of tax benefits recorded as a result of the finalizing and filing of our 2005 federal and state tax returns. Our deferred tax assets primarily consist of net operating loss carry forwards and research and development tax credits. We have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain.

Liquidity and Capital Resources

As of September 30, 2006, cash and cash equivalents were approximately $15.9 million, as compared to $2.3 million at December 31, 2005. Investments consisting of U.S. government and agency securities were approximately $3.0 million, as compared to $0 at December 31, 2005. These net increases were primarily due to the proceeds we received from the initial public offering of our common stock.

Net cash used in operating activities was approximately $9.4 million for the nine months ended September 30, 2006. The net cash used in operating activities was attributable to a net loss of approximately $9.5 million, as adjusted for the effect of non-cash items of $1.3 million and changes in operating assets and liabilities of approximately $1.2 million. The changes in operating assets and liabilities consisted of cash inflows from the decrease in accounts receivable and increase in accounts payable, which were more than offset by the building of inventory, increase in prepaid expenses, and decreases in accrued expenses and deferred liabilities.

Net cash used in investing activities was approximately $7.2 million for the nine months ended September 30, 2006. The net cash used in investing was attributable to capital expenditures of $3.7 million related to the construction project to expand our manufacturing capabilities, plus equipment for the increase in production demand. We expect to

spend an additional $0.5 million in the next twelve months to complete the expansion project and to purchase related equipment. In addition, we purchased the product rights associated with Valstar for $0.5 million. We purchased approximately $5.9 million in investments consisting of U.S government and agency securities. We sold approximately $3.0 million in investments in U.S government and agency securities.

Net cash provided by financing activities was approximately $30.1 million for the nine months ended September 30, 2006. As a result of our initial public offering in February 2006, we generated approximately $31.6 million of proceeds net of underwriter fees from the issuance of our common stock and approximately $100,000 from the issuance of stock as a result of stock option exercises.

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We paid approximately $1.3 million in offering fees during 2005, resulting in total net proceeds from the initial public offering of $30.3 million. Subsequent to the initial public offering of our common stock, we repaid in full the approximately $1.5 million outstanding amount under our line of credit with Merrill Lynch.

We anticipate that cash flows from sales of Vantas may reduce our need for additional financing. However, we expect our cash requirements to continue to increase in the foreseeable future as we continue to sponsor additional clinical trials, seek regulatory approvals, and develop, manufacture and market our current product candidates. As we continue to expand our commercial organization, expand our research and development efforts and pursue additional opportunities, we anticipate significant cash requirements for the hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure. The amount and timing of cash requirements will depend on market acceptance of our lead product, Vantas, as well as regulatory approval and market acceptance of our product candidates, if any. The resources we devote to researching, developing, formulating, manufacturing, commercializing and supporting our product candidates, and our ability to enter into third-party collaborations will also affect our cash requirements.

We believe that our existing cash, the cash generated from our initial public offering, cash generated from future sales of Vantas, and our line of credit will be sufficient to fund our operations for at least the next 12 months. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities. In addition, we may receive revenue from our sublicense agreement.

We may finance future cash needs through strategic collaboration agreements, the sale of equity securities or additional debt financing. We may not be successful in obtaining collaboration agreements, additional debt or equity financing or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that in the future our existing cash resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or delay the launch of our product candidates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

To date, all of our sales have been denominated in U.S. dollars. Although we do conduct some clinical and safety studies with vendors located outside the United States, all of these expenses are paid in U.S. dollars. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows. Accordingly, we believe that there is no material exposure to risk from changes in foreign currency exchange rates.

We hold no derivative financial instruments and do not currently engage in hedging activities.

Our exposure to interest rate risk is related to the investment of our excess cash in highly liquid financial investments with original maturities of three months or less. We invest in money market funds in accordance with our investment policy, which is designed to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy also specifies credit quality standards for our investments. Due to the short term nature of our investments, we believe that there is no material exposure to interest rate risk arising from them.

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2006 and, based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective. Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the Securities Exchange Act), is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Securities Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as

appropriate to allow timely decisions regarding required disclosure.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As of September 30, 2006, we were not subject to any pending or, to our knowledge, threatened litigation.

Item 1A. Risk Factors

We have not updated any risk factors in our Form 10-Q for the quarterly period ended September 30, 2006. The last update was included in our Form 10-Q for the quarterly period ended June 30, 2006. The complete list of risk factors are disclosed in our Form 10-K for the fiscal year ended December 31, 2005.

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Other Information

None

Item 6. Exhibits and Reports on Form 8-K

The following exhibits are filed herewith:

10.1	Investment and Shareholders Agreement Spepharm Holding B.V.	31-51
10.2	License and Distribution Agreement between Valera Pharmaceuticals, Inc. and Spepharm Holding B.V.	52-69
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002	70
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002	71
32	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	72

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VALERA PHARMACEUTICALS, INC

Dated: November 9, 2006

By: /s/ David S. Tierney, M.D.

David S. Tierney, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Dated: November 9, 2006

By: /s/ Andrew T. Drechsler

Andrew T. Drechsler
Chief Financial Officer
(Principal Financial and Accounting Officer)