Valera Pharmaceuticals Inc
Form 10-Q
April 28, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended: March 31, 2006

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 No

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

Large accelerated filer Accelerated filer Non-accelerated filer

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

Yes No

As of April 1, 2006, there were 14,885,546 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”), “Quantitative and Qualitative Disclosures about Market Risk” in Part I, Item 3, and “Unregistered Sales of Equity Securities and Use of Proceeds” in Part II, Item 2, 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 businesses 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 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 U.S. 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)

	March 31, 2006	December 31, 2005
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 29,310	$ 2,340
Accounts receivable, net of allowances of $462 at March 31, 2006 and $385 at December 31, 2005	4,052	4,488
Inventories, net	3,888	3,191
Prepaid expenses and other current assets	901	726
Total current assets	38,151	10,745
Property, plant and equipment, net of accumulated depreciation of $1,506 at March 31, 2006 and $1,374 at December 31, 2005	5,651	4,194
Deferred offering costs	—	1,378
Deferred financing costs	107	124
Security deposits	91	91
Product rights	525	—
Total assets	$ 44,525	$ 16,532
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,489	$ 1,421
Accrued liabilities	3,930	4,607
Note payable	—	1,525
Deferred revenue – current	37	329
Capital lease obligations – current	13	18
Total current liabilities	7,469	7,900
Other non current liabilities	150	—
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 March 31, 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 $20,221 at March 31, 2006 and December 31, 2005 respectively	—	15,082
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 March 31, 2006 and December 31, 2005, respectively	—	11,239
Shareholders' equity (deficit):		
Common stock, $0.001 par value; 30,000 authorized, 14,886 and 1,667 issued and outstanding at March 31, 2006 and December 31, 2005, respectively	15	2
Additional paid-in-capital	78,364	8,696
Deferred stock-based compensation	—	(630)
Accumulated deficit	(41,773)	(39,661)
Total shareholders' equity (deficit)	36,606	(31,593)
Total liabilities and shareholders' equity (deficit)	$ 44,525	$ 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 March 31,	
	2006	**2005**
Net product sales	$ 5,525	$ 7,686
Licensing revenue	7	9
Total net revenue	5,532	7,695
Operating costs and expenses:		
Cost of product sales	1,461	1,023
Research and development	2,017	1,060
Selling and marketing	2,709	2,501
General and administrative	1,631	1,388
Total operating costs and expenses	7,818	5,972
(Loss) income from operations	(2,286)	1,723
Interest income	211	15
Interest expense	(27)	(1)
(Loss) income before income taxes	(2,102)	1,737
Provision for income taxes	10	160
Net (loss) income	$ (2,112)	$ 1,577
Basic net (loss) income per share	$ (0.22)	$ 0.95
Diluted net (loss) income per share	$ (0.22)	$ 0.14
Basic weighted average number of shares outstanding	9,666	1,667
Diluted weighted average number of shares outstanding	9,666	11,220

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 Three Months Ended March 31, 2006
(in thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value				
Balances at December 31, 2005	1,667	$ 2	$ 8,696	$ (630)	$ (39,661)	$ (31,593)
Net loss					(2,112)	(2,112)
Issuance of common stock	13,219	13	70,117			70,130
Exercise of stock options			1			1
Elimination of deferred compensation related to adoption of FAS 123(R)			(630)	630		
Expense related to options granted to non-employees			6			6
Compensation expense related to employee stock options			174			174
Balances at March 31, 2006	14,886	$ 15	$ 78,364	$	$ (41,773)	$ 36,606

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)

	Three Months Ended March 31,	
	2006	**2005**
Operating activities		
Net (loss) income	$ (2,112)	$ 1,577
Adjustments to reconcile net (loss) income to net cash used in operating activities		
Depreciation and amortization	132	95
Amortization of deferred financing fees	17	—
Allowances for accounts receivable	77	107
Expense related to options granted to non-employees	6	14
Stock based compensation	174	235
Changes in assets and liabilities which provided (used) cash		
Accounts receivable	359	(4,525)
Inventories	(697)	(970)
Prepaid expenses and other current assets	(175)	33
Security deposits	—	(87)
Accounts payable	2,068	(837)
Accrued liabilities	(677)	1,376
Other non-current liabilities	150	—
Deferred revenue	(292)	300
Net cash used in operating activities	(970)	(2,682)
Investing Activities		
Capital expenditures	(1,589)	(354)
Purchase of product rights	(525)	—
Net cash used in investing activities	(2,114)	(354)
Financing Activities		
Net proceeds from issuance of common stock	31,584	—
Payment of capital lease obligations	(5)	(7)
Payment of notes payable	(1,525)	—
Deferred offering costs	—	(593)
Net cash provided by (used in) financing activities	30,054	(600)

Net increase (decrease) in cash and cash equivalents	26,970	(3,636)
Cash and cash equivalents at beginning of period	2,340	5,053
Cash and cash equivalents at end of period	$ 29,310	$ 1,417

Schedule of noncash investing and financing activities:

Conversion of preferred stock into common stock	$ 39,925	$

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. Prior to November 2004, the Company operated as a development-stage company and did not generate any substantial revenue. In November 2004, the Company exited the development stage when it began selling its initial product Vantas®. The Company operates in a single business segment and through March 31, 2006, all of its product sales and assets were in the United States.

Recent Developments

On January 27, 2006, the Company effected a one-for-six reverse stock split. In connection with the reverse stock split, every outstanding six shares of the Company's common stock were replaced with one share of the Company's common stock. All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these financial statements and notes to the financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis. Effective upon consummation of the initial public offering, the Company reduced the number of common shares authorized for issuance to 30,000,000 and the number of preferred shares authorized for issuance to 5,000,000.

On February 7, 2006, the Company closed its initial public offering (IPO). The Company issued 3,862,500 shares at $9.00 per share resulting in net proceeds of approximately $30.3 million after underwriter discounts and offering expenses. As a result of the initial public offering, all outstanding shares of the Company's preferred stock converted into 9,355,714 shares of common stock. Thus, immediately following the offering, the Company had 14,885,296 common shares outstanding. In February 2006, the Company paid in full its note payable to Merrill Lynch in the amount of approximately $1.5 million.

In March 2006, the Company announced that Paladin Labs received approval from Health Canada to market the Company's product Vantas®. In October 2002, the Company granted Paladin Labs an exclusive, royalty-bearing license for the marketing, distribution, and sale of Vantas® in Canada. Paladin has indicated that it anticipates launching Vantas® in the second half of 2006.

On March 31, 2006, the Company completed its acquisition of the New Drug Application and other assets associated with the product known as Valstar® (valrubicin) in the United States and Valtaxin in Canada for the purchase price of $525,000. The Company expects to begin marketing the product in the United States by the end of the fourth quarter of 2006. Valstar is a bladder instillation approved to treat bladder cancer that is no longer responsive to conventional treatment such as surgery and / or topical drug application.

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 generally accepted accounting principles in the United States 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 our 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 March 31, 2006, the results of the Company's operations for the three months ended March 31, 2006 and 2005, and the Company's cash flows for the three months ended March 31, 2006 and 2005.

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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. At March 31, 2006, the Company had substantially all of its cash and cash equivalents deposited with one financial institution.

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.

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.

Deferred Offering and Financing Costs

Costs incurred in relation to the Company's initial public offering were deferred as of 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.

Net Product Sales

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

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VALERA PHARMACEUTICALS, INC

NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

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 March 31, 2006, the Company had a reserve of approximately $276,000 for returns and adjustments, of which $26,000 related to sales made in 2005 and $250,000 related to sales made in 2006. As of March 31, 2006 and December 31, 2005, there was approximately $71,000 and $300,000 of Vantas, respectively, at distributors.

For the three months ended March 31, 2006	**Distributors**	**Physicians**	**Total**
		(In thousands)	
Allowance balance at December 31, 2005	$ 19	$ 320	$ 339
Provision related to sales for Fiscal 2006	7	398	405
Returns and adjustments related sales in Fiscal 2004		(19)	(19)
Returns and adjustments related sales in Fiscal 2005	(1)	(293)	(294)
Returns and adjustments related sales in Fiscal 2006	(2)	(153)	(155)
Allowance balance at March 31, 2006	$ 23	$ 253	$ 276

For the three months ended March 31, 2005	**Distributors**	**Physicians**	**Total**
		(In thousands)	
Allowance balance at December 31, 2004	$ 28	$ 316	$ 344
Provision related to sales for Fiscal 2005		540	540
Returns and adjustments related sales in Fiscal 2004		(168)	(168)
Returns and adjustments related sales in Fiscal 2005		(182)	(182)
Allowance balance at March 31, 2005	$ 28	$ 506	$ 534

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.

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NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

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 March 31, 2006 and December 31, 2005, the Company deferred approximately $24,000 and $329,000 of revenue and recorded $4,000 and $44,000 of assets, respectively, 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. 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.

Advertising Costs

The Company charges advertising costs to operations as incurred.

Product Rights

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 March 31, 2006, the Company has recorded the product rights at their purchase price of $525,000. Product rights are stated at cost, less accumulated amortization, and are amortized over their estimated useful lives using the straight-line method. The Company periodically reviews the original estimated useful lives of long-lived assets and makes adjustments when appropriate. The Company is currently in the process of determining the useful life of the Valstar products rights.

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VALERA PHARMACEUTICALS, INC

NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Stock-Based Compensation

The Company adopted SFAS No. 123(R) 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. 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 has been eliminated. As of March 31, 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

In accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” (“SFAS 144”), 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 March 31, 2006.

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 three months ended March 31, 2006 and 2005 from its product Vantas. All of the sales were generated and distributed in the United States. In addition, for the three months ended March 31, 2006 and 2005, one customer accounted for 5.4% and 5.9%, respectively, of the Company's net unit sales and 1.1% and 11.2% of its outstanding receivables at March 31, 2006 and 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.

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VALERA PHARMACEUTICALS, INC

NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

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.

Recently Issued Accounting Pronouncements

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.

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections”, which replaces APB Opinion No. 20, “Accounting Changes” and SFAS No. 3, “Reporting Accounting Changes in Interim Financial Statements”. This pronouncement applies to all voluntary changes in accounting principle, and revises the requirements for accounting for and reporting a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle, unless it is impracticable to do so. This pronouncement also requires that a change in the method of depreciation, amortization, or depletion for long-lived, non-financial assets be accounted for as a change in accounting estimate that is effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Statement does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. The Company adopted SFAS No. 154 on January 1, 2006. The adoption of SFAS No. 154 did not have a material impact on the Company’s financial statements.

Note 3. Inventory

Inventories consist of the following:

	March 31, 2006	December 31, 2005
	(unaudited)	
	(in thousands)	
Raw materials	$ 599	$ 463
Work-in-process	2,853	2,426
Finished goods	436	302
	$ 3,888	$ 3,191

The preceding amounts are net of inventory reserves of approximately $1.0 million and $1.2 million at March 31, 2006 and 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 4. Property, Plant and Equipment

Property, plant and equipment consists of the following:

	Useful Lives	March 31, 2006	December 31, 2005
		(unaudited)	
		(in thousands)	
Laboratory equipment	5 years	$ 1,583	$ 1,531
Furniture and Fixtures	7 years	161	161
Office equipment	5 years	108	108
Computer equipment	3 years	429	417
Computer software	3 years	256	200
Construction in process		3,995	2,526
Leasehold improvements	1-10 years	625	625
		7,157	5,568
Less accumulated depreciation and amortization		(1,506)	(1,374)
Property, Plant and equipment, net		$ 5,651	$ 4,194

Depreciation expense and amortization for the three months ended March 31, 2006 and 2005 was approximately $132,000 and $95,000, respectively. There were property, plant and equipment assets totaling approximately $68,000 at March 31, 2006 and December 31, 2005, respectively, subject to capital lease obligations with accumulated amortization of approximately $57,000 and $54,000 at March 31, 2006 and 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 expansion is expected to be completed in the second half of 2006.

Note 5. Deferred Offering and Financing Costs

The Company had deferred offering costs of $0 and approximately $1.4 million at March 31, 2006 and December 31, 2005, respectively. The Company netted its prior 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 $107,000 and $124,000 at March 31, 2006 and December 31, 2005, respectively. Deferred financing costs are being amortized over the two year term of the loan.

Note 6. 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. Borrowings under the line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.75% (8.58% at March 31, 2006). The Company is subject to certain covenants under the line of credit. In connection with the line of credit, the Company pledged all of its assets, with the exception of intellectual property, to Merrill Lynch. At March 31, 2006 and December 31, 2005,

the Company had $0 and approximately $1.5 million outstanding under the 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 7. Capitalization

Common Stock

The Company had 14,885,546 and 1,667,082 shares of common stock, par value $0.001, outstanding at March 31, 2006 and 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 three months ended March 31, 2006, 250 shares of common stock were issued as a result of a stock option exercise.

Convertible Preferred Stock

As of March 31, 2006, all of the Company’s convertible preferred stock was converted into common stock. In February 2006, the Company filed an amended and restated Certificate of Incorporation that removed the designations, rights and obligations of the convertible preferred stock.

Note 8. Stock-Based Compensation

The Company adopted SFAS No. 123(R) 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. 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% 4.34%
Expected volatility	61.1%
Expected dividend yield	0.0%
Expected life (in years)	6.25
Forfeiture rate	4.0%
Weighted average fair value at date of grant	$6.33

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.

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VALERA PHARMACEUTICALS, INC

NOTES TO FINANCIAL STATEMENTS – UNAUDITED (Continued)

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.

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

	Three Months Ended March 31, (in thousands)	
	2006	2005
Method used to account for employee stock-based compensation	Fair Value	Intrinsic
Employee Stock-based compensation under SFAS No. 123 (R)	$ 174	$ 235

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

	Three Months Ended March 31, 2005 (in thousands, except per share amounts)
Net (loss) income to common stock holders – as reported	$ 1,577
Add: non-cash employee compensation as reported	235
Deduct: total employee stock-based compensation expense determined under fair value based method for all awards	(151)
Net (loss) income to common stockholders – pro-forma	$ 1,661
Basic (loss) income per share – as reported	$ 0.95
Basic (loss) income per share – pro-forma	$ 1.00
Diluted (loss) income per share – as reported	$ 0.14
Diluted (loss) income per share – pro-forma	$ 0.15

The following table is a summary of stock option activity under the Company's Equity Incentive Plan for the Company's common stock as of December 31, 2005, and changes during the three months ended March 31, 2006:

	Common Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted Average Contractual Life
Outstanding at December 31, 2005	1,265,849	$ 4.25		
Granted	220,600	$ 9.08		

Exercised	(250)	$	3.00		
Forfeited	(22,017)	$	8.24		
Outstanding at March 31, 2006	1,464,182	$	4.92	$ 840	8.1
Exercisable at March 31, 2006	609,348	$	3.15	$ 236	7.6

The total intrinsic value of the options exercised during the three months ended March 31, 2006 was $3,300. As of March 31, 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 three months ended March 31, 2006 and 2005, the Company granted a total of 0 and 3,333 options, respectively, to certain consultants. The Company has accounted for non-employee options in accordance with EITF 96-18 and, accordingly, recorded non-cash expense of approximately $6,000 and $14,000 for the three months ended March 31, 2006 and 2005, respectively.

For the three months ended March 31, 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
March 31, 2006	220,660	$ 9.08	$ 5.57	
March 31, 2005	14,499	$ 6.00	$ 16.20	$ 10.20

Note 9. Income Taxes

The provision for federal, state and local income taxes for the three months ended March 31, 2006 and 2005 was $10,000 and $160,000, respectively, with effective tax rates of 0.5% and 9.2%, 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 March 31, 2006 and December 31, 2005, a valuation allowance was recorded to fully offset the net deferred tax asset.

Note 10. Net Income (Loss) Per Share

The Company computes its basic net income (loss) per share in accordance with SFAS No. 128, "Earnings per Share" ("SFAS 128"). Under the provisions of SFAS 128, basic net income (loss) per common share ("Basic EPS") is computed 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 as of March 31, 2006 have been excluded from the computation of diluted net income (loss) per share as their effect would be anti-dilutive.

	Three Months Ended March 31,			
	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	$ (2,112)	9,666	$ 1,577	1,667
Effect of preferred stock conversion				8,660
Effect of dilutive stock options				893

Diluted net (loss) income per share factors	$ (2,112)	9,666	$ 1,577	11,220
Basic net (loss) income per share	$ (0.22)		$ 0.95	
Diluted net (loss) income per share	$ (0.22)		$ 0.14	

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VALERA PHARMACEUTICALS, INC

NOTES TO FINANCIAL STATEMENTS UNAUDITED (Continued)

Note 11. Related Party Transactions

Sanders Morris Harris, Inc. 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 $0 and $300,000 during the three months ended March 31, 2006 and 2005, respectively from BioPro. The Company did not make any payments to Alpex during the three months ended March 31, 2006 or 2005.

Note 12. Acquisition of Product

In March 2006, the Company acquired certain assets of Anthra Pharmaceuticals associated with its valrubicin business in the U.S. 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 U.S., the product was distributed under the trademark Valstar.

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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 Company's 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. The Company undertakes 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.

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 luteinizing 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 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.

In addition to Vantas, we are developing a pipeline of proprietary product candidates for indications that include central precocious puberty, acromegaly, opioid addiction, interstitial cystitis, nocturnal enuresis and bladder cancer. Several of our product candidates also utilize our Hydron 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, including for clinical trial costs, on the development of our product candidates. We plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe. In March 2006, the Company announced that Paladin Labs received approval from Health Canada to market our Vantas product in Canada. We expect our costs to increase significantly as we continue to develop and ultimately commercialize 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 to achieve and maintain profitability.

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.

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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 expect our research and development expenses when measured as a percentage of total operating expenses, to continue to decline due to the fact we will be selling our products and growing our infrastructure. We do not disclose estimated research and development costs for product candidates that are not yet in Phase III clinical trials. We estimate that we will incur approximately $1.0 million of expenses, in addition to costs previously incurred, in order to complete Phase III trials for our Supprelin-LA implant for the treatment of central precocious puberty and to complete the regulatory process for having the implant approved for the indication to commercialize a product in the United States. These estimates assume the completion of a single Phase III trial which is currently underway.

Product Sales and Costs

We generate revenues from sales of Vantas, our lead product. We began commercial sales of Vantas in November 2004. Currently, all sales are 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 may be affected by physician utilization, pricing pressure 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 cost, 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 net average selling price to our customers was $2,604 for the six months ended June 30, 2005, it declined to $2,099 during the three months ended September 30, 2005 and further declined to $1,801 per unit in the fourth quarter of 2005. For the three months ended March 31, 2006 and 2005, the average net average selling price of Vantas was $1,620 and $2,628, respectively. We expect future reimbursement levels to continue to decline, which will have an adverse effect on our net product sales. In some states, where the reimbursement rate for Vantas is based on ASP, the reimbursement levels will continue to decline because the ASP for Vantas will decline as we sell Vantas at prices below the reimbursement rate. In most states, however, the reimbursement rates for Vantas are even lower because the Medicare carriers in those states now apply 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.” The reimbursement rate for Vantas, as determined by Medicare carriers, is lower in LCA states than the reimbursement rate in non-LCA states, resulting in a lower sales price in LCA states.

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 the Company’s 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.

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Research and Development Expenses

Our research and development expenses consist of costs incurred for company-sponsored and collaborative research and development activities. 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.

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

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 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 March 31, 2006.

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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

The Company adopted SFAS No. 123(R) 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. 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.

Results of Operations

Three months ended March 31, 2006 compared with three months ended March 31, 2005

Net Product Sales. Net product sales for the three months ended March 31, 2006 were approximately $5.5 million as compared to $7.7 million for the three months ended March 31, 2005. The 28% decrease in net product sales was a direct result of lower net average selling prices due to decreased Medicare reimbursement rates for our Vantas product. For the three months ended March 31, 2006, we sold 3,412 units of Vantas at a net average selling price of $1,620 per unit as compared to 2,925 units at a net average selling price of $2,628 for the same period in 2005. Thus, actual unit sales of Vantas increased by 17%, or 487 units, for the three months ended March 31, 2006, as compared to the same period in the prior year.

Vantas is currently eligible for insurance reimbursement coverage. Sales of Vantas in the three months ended March 31, 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 cost, which is typically higher than ASP. Effective July 2005, Vantas received an established ASP, which resulted in a lower reimbursement rate.

We expect the reimbursement levels for Vantas to continue to decline, which will have an adverse effect on our net product sales. In some states, where the reimbursement rate for Vantas is based on ASP, the reimbursement levels will continue to decline because the ASP for Vantas will decline as we sell Vantas at prices below the reimbursement rate. In most states, however, the reimbursement rates for Vantas are even lower because the Medicare carriers in those states now apply a methodology known as the least costly alternative, or LCA, to Vantas. The reimbursement rate for Vantas, as determined by the Medicare carriers, is lower in LCA states than the reimbursement rate in non-LCA states, resulting in a lower sales price in LCA states.

Licensing Revenue. For the three months ended March 31, 2006 and 2005, we recorded licensing revenues of approximately $7,000 and $9,000, respectively, from Hydron Technologies under a licensing arrangement.

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Cost of Product Sales. Our cost of product sales for the three months ended March 31, 2006 and 2005 was approximately $1.5 million and $1.0 million, respectively. Gross margins as a percentage of net product sales for the three months ended March 31, 2006 and 2005 were 74% and 87%, respectively. Unit sales of Vantas for the comparable period increased by approximately 17%, while the cost of product sales increased by approximately 43%. The increase in cost of product sales was due to the fact that the initial raw material costs associated with the inventory build-up of Vantas before commercialization were originally expensed to research and development as required by generally accepted accounting principles in the United States, thus lowering the initial cost of the product. Following FDA approval of Vantas, raw material costs were capitalized into inventory, thus increasing the cost of the product and lowering the gross margin. This increase in the raw material costs, as well as decreased lower average selling prices of Vantas due to lower Medicare reimbursement levels, yielded lower gross margins for the three months ended March 31, 2006 as compared to the three months ended March 31, 2005.

Research and Development Expense. Research and development expense for the three months ended March 31, 2006 and 2005, was approximately $ 2.0 million and $1.1 million, respectively. Expenses related to clinical trials and research projects pursuant to contracts with research institutions and clinical research organizations represented 45% of our total research and development expense for the three months ended March 31, 2006 compared to 48% of our research and development expense for the three months ended March 31, 2005. Internal research and development expense was approximately 55% and 52% of our total research and development expense for the three months ended March 31, 2006 and 2005, respectively. The increase in internal research and development expense was primarily due to an increase in materials for clinical programs and an increase in salaries and benefits as we continue to add resources to this function. Research and development expense for the three months ended March 31, 2006 also increased by approximately $150,000 as a result of the Company acquiring the Supprelin brand name. We expect to continue to spend significant amounts on the development of our product candidates, including clinical trial costs for a Phase III trial for our VP003 (Octreotide) implant which will commence in the second half of 2006. We plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe.

Selling and Marketing Expense. Selling and marketing expense for the three months ended March 31, 2006 and 2005 was approximately $2.7 million and $2.5 million, respectively. The increase was predominantly the result of increased salaries and the related expenses of adding employees to our sales force. We expect our selling and marketing expense to increase in future periods as we continue to grow our commercial organization and marketing activities in support of our lead product Vantas, the recently acquired Valstar, as well as future product candidates.

General Administrative Expense. General administrative expense for the three months ended March 31, 2006 and 2005, was approximately $1.6 million and $1.4 million, respectively. The increase was primarily due to an increase in rent, directors and officer’s insurance expense, and professional fees. The rent increased as a result of leasing additional space in order to expand our operations. Professional fees increased as a result of accounting and legal fees related to the Company’s acquisition of the Valstar assets and the Supprelin brand name.

Net Interest Income. Net interest income was approximately $184,000 and $14,000 for the three months ended March 31, 2006 and 2005, respectively. The increase was primarily due to the increased cash balance resulting from the proceeds of the initial public offering of our common stock in February 2006.

Income Taxes. Income tax expense was approximately $10,000 and $160,000 for the three months ended March 31, 2006 and 2005, respectively. As a result of the loss of approximately $2.1 million for the three months ended March 31, 2006, as well as the previous net operating losses since the our inception, we did not record any federal provision for income taxes during the period ended March 31, 2006. We did record a provision of $10,000 during the period for state taxes subject to alternative minimum tax. The $160,000 provision for taxes at March 31, 2005 was a result of the income before income taxes of approximately $1.7 million for the three months ended March 31, 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.

Liquidity and Capital Resources

As of March 31, 2006, cash and cash equivalents were approximately $29.3 million, as compared to $2.3 million as of December 31, 2005. This net increase was primarily due to the proceeds we received from the initial public offering of our common stock.

Net cash used in operating activities was approximately $1.0 million for the three months ended March 31, 2006. The net cash used in operating activities was attributable to a net loss of approximately $2.1 million, as adjusted for the effect of non-cash items of $0.4 million and changes in operating assets and liabilities of approximately, $0.7 million. The changes in operating assets and liabilities consisted of cash inflows from the collection of accounts receivable and the 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.

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Net cash used in investing activities was approximately $2.1 million for the three months ended March 31, 2006. The net cash used in investing was attributable to capital expenditures related to the construction project to expand our manufacturing capabilities, plus equipment for the increase in production demand. We expect to spend an additional $5.0 million in the next twelve months to complete the expansion project. In addition, we purchased the product rights associated with Valstar for $0.5 million.

Net cash provided by financing activities was approximately $30.1 million for the three months ended March 31, 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. The Company 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 will 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 debt financing. We established a line of credit in October 2005. 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 March 31, 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.

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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 March 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As of March 31, 2006, we were not subject to any pending or, to our knowledge, threatened litigation.

Item 1A. Risk Factors

There has been no material change to the risk factors required to be disclosed by us in our Form 10-K for the fiscal year ended December 31, 2005.

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

Unregistered Sales of Equity Securities

During the three months ended March 31, 2006, following the exercise of options to purchase shares of common stock that had been granted under the Company’s Equity Incentive Plan by an employee, we issued an aggregate of 250 shares of restricted common stock for an aggregate purchase price of approximately $750. This sale of common stock was made pursuant to the exemption from the registration requirements of the Securities Act afforded by Rule 701.

Use of Proceeds

On February 1, 2006, our registration statement on Form S-1 (Reg. No. 333-123288) covering the offering of 3,862,500 shares of our common stock was declared effective. The offering closed on February 7, 2006 and did not terminate before any securities were sold. The aggregate purchase price of the common stock offered and sold by the Company was $34.8 million.

We incurred expenses in connection with the offering of approximately $4.5 million, which consisted of direct payments of: (i) $1.9 million in legal, accounting and printing fees; (ii) $2.4 million in underwriters' discounts, fees and commissions; and (iii) $0.2 million in miscellaneous expenses. After deducting these expenses, we received net offering proceeds of approximately $30.3 million.

We used approximately $1.5 million of the offering proceeds to repay borrowings we had under a line of credit with Merrill Lynch. We intend to use the remaining proceeds (i) to advance our product candidates through preclinical and clinical trials, (ii) for commercialization of our products, (iii) for general corporate purposes including the acquisition or in-licensing of products or product candidates, and (iv) for working capital. We regularly assess the specific uses and allocations of the offering proceeds.

Item 3. Defaults Upon Senior Securities

None

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

During the fiscal quarter ended March 31, 2006 and in connection with our preparations for our initial public offering, stockholder consents were sought for the following actions pursuant to Section 228 of the Delaware

General Corporation Law:

- To approve a six-for-one reverse split of our common stock;
- To approve the classification of our Board of Directors into three classes, and to elect the following persons to serve as the initial Class I, Class II and Class III directors:

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- Mr. Jerome I. Feldman, Dr. Hubert E. Huckel, and Mr. Ogden R. Reid as Class I directors;
- Dr. David R. Dantzker, Mr. James C. Gale, and Mr. Howard Silverman as Class II directors; and
- Mr. Jeffrey M. Krauss, Mr. John T. Spitznagel, and Dr. David S. Tierney as Class III directors;

- To approve an amendment and restatement of our Certificate of Incorporation, which among other things reduced the number of shares of common and preferred stock authorized for issuance, removed the designations, rights and privileges of the preferred stock and provided for the classification of our board of directors;

- To approve an amendment and restatement of our Bylaws;

- To approve an increase in the number of shares available for issuance under our Equity Incentive Plan from 1,308,333 to 1,833,333;

- To approve the conversion of all of our issued and outstanding preferred stock into shares of common stock; and

- To waive certain registration rights held by our stockholders.

Each of the foregoing matters was approved in January 2006 by the holders of a majority of our outstanding shares of capital stock, including the holders of at least eighty percent (80%) of the outstanding shares of our Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock

Item 5. Other Information

None

Item 6. Exhibits and Reports on Form 8-K

The following exhibits are filed herewith:

31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	27
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	28
32	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	29

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 April 28, 2006

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

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

Dated April 28, 2006

By: /s/ Andrew T. Drechsler

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